UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	MD 15-02641-PHX-DGC
Lisa Hyde and Mark Hyde, a married couple, Plaintiffs,	Phoenix, Arizona **September 19, 2018**
v.	CV 16-00893-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation, and Bard Peripheral Vascular, an Arizona corporation, Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 2 - P.M. SESSION

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Proceedings Reported by Stenographic Court Reporter
Transcript Prepared with Computer-Aided Transcription

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I N D E X

EXAMINATION

EXHIBITS

P R O C E E D I N G S

(Recess was taken until 12:58. Proceedings resumed in open court with the jury present.)

12:59:42 THE COURT: Thank you. Please be seated.

You may continue, Mr. Rogers.

MR. ROGERS: Thank you, Your Honor.

Dr. Hurst, are you ready?

THE WITNESS: Yes, sir.

DARREN R. HURST, M.D.,

resumed as a witness, after having been previously sworn or affirmed, and was examined and testified as follows:

C R O S S - E X A M I N A T I O N (CONTINUED)

BY MR. ROGERS:

12:59:53 Q Dr. Hurst, we're kind of in the home stretch so we'll try and wrap this up.

I wanted to ask you now a few questions about caudal migration. Am I correct that when you were answering questions from Mr. O'Connor that you testified that you

13:00:09 estimated that Mrs. Hyde's filter migrated in the caudal direction approximately 5 millimeters; is that right?

A Very minimal, yes.

Q And I believe you said that that is not a predominant issue in this case; is that correct?

13:00:24 A That's correct.

13:00:25 Q And, Doctor, would you agree with me that when we are breathing in and out, that the vena cava moves?
A It does, yes.
Q And so on an imaging study, if we are breathing in and
13:00:36 out, if the vena cava's in a different position can that cause on the imaging for the filter that's inside the vena cava to be in different positions?
A Yes, it can.
Q Are you familiar with the SIR standards for tracking of
13:00:50 complications with filters?
A Yes.
Q And would you agree with me that according to that organization that the standard for tracking of caudal migration requires that the migration be at least two
13:01:03 centimeters; is that correct?
A Yes, that's correct.
Q And so the migration that you would have observed in your opinion in Mrs. Hyde's case would not be considered a trackable event by the Society of Interventional Radiologists;
13:01:16 correct?
A I wouldn't consider it a trackable event; correct.
MR. ROGERS: Could we pull up Exhibit 8325, please.
Is it up? I'm sorry, my screen must not be working. I don't know why that is.
13:01:50 THE COURTROOM DEPUTY: It's on the monitors at your

13:01:52 table; right?

MR. ROGERS: Yeah. This one's just dark.

THE COURTROOM DEPUTY: It just got turned off.

MR. ROGERS: Turned off. Would it be that

13:02:00 complicated? Okay. Thank you.

Your Honor, I move this document into evidence.

MR. O'CONNOR: No objection, Your Honor. I'm sorry.

THE COURT: Admitted.

(Exhibit 8325 admitted.)

13:02:20 BY MR. ROGERS:

Q Dr. Hurst, you have in front of you Exhibit 8325, and you would agree that that is the IFU for the Eclipse filter; correct?

A Yes, the front page.

13:02:30 Q And you are familiar with this document; right?

A Yes.

Q And I believe you were critical of this document in your testimony on direct; is that right?

A Yes.

13:02:40 Q And specifically -- well, I'll skip that.

MR. ROGERS: Can we go to section E, please.

Can we pull that out.

BY MR. ROGERS:

Q And, Doctor, do you see this section that's on your

13:02:55 screen?

13:02:56 A Yes.

MR. ROGERS: And, Your Honor, may we publish for the jury?

THE COURT: Yes.

13:03:03 BY MR. ROGERS:

Q And, Doctor, you're familiar with this section called "Warnings" in the instructions for use; correct?

A Correct.

Q And if we look at this --

13:03:11 MR. ROGERS: Let's just go down a few, please.

BY MR. ROGERS:

Q There's several bullets; right? And looking at bullet number 8, do you see that?

A I do.

13:03:20 MR. ROGERS: And could you pull that out, please.

BY MR. ROGERS:

Q And, Doctor, you would agree that this says: "Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac

13:03:38 complications with vena cava filters requiring retrieval of the fragment utilizing endovascular and/or surgical techniques."

Did I read that correctly?

A Yes.

13:03:48 Q And you would agree that filter fractures are a known

13:03:51 complication of vena cava filters?
A What do you mean by known complication?
Q It would mean that it's known within the medical community.
13:03:58 A It is known, but by saying in this IFU that it's a known complication, the assumption is that it is similar to other devices that were previously used.
Q All right. And, Doctor, would you agree, though, that this says there can be serious pulmonary and cardiac
13:04:15 complications with vena cava filters?
A Serious pulmonary and cardiac complications were extremely rare. This doesn't describe how often they occur.
Q And you would agree that this says that you may have to use surgical techniques to retrieve these pieces; is that
13:04:29 correct?
A This was a unique complication of that device, yes.
Q And you would agree with me that based on this information, as a doctor, you can certainly discern that a fragment can travel to the heart; is that correct?
13:04:40 A Yes.
Q And it may need to be removed?
A Correct.
Q And would you agree that that is precisely what happened in Mrs. Hyde's case?
13:04:48 A That is what happened.

13:04:52 MR. ROGERS: All right. And let's -- you can pull that down, and let's pull out the next section, number 9. I'm sorry, number 9. Apologize.

BY MR. ROGERS:

13:04:59 Q And, Doctor, would you agree with me that this says: "Movement, migration, or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported."

Did I read that correctly?

13:05:16 A Again, yeah, you did read it correctly.

Q And you would agree it says: "There have also been reports of caudal migration of the filter."

Did I read that correctly?

A Yes. Again, by saying known complications, you're not

13:05:28 really giving an incidence of when these complications occur and the degree of seriousness of the complications.

Q And are you aware of any manufacturer of IVC filters that includes these incidence rates that you're talking about?

A No, actually they don't. However, the previous IFUs only

13:05:45 listed probably about four complications for the devices, where this particular IFU lists almost 30.

And by saying "known complication" over and over again in your IFU, basically you're rendering that -- I'm sorry. By saying your wording in this IFU, it doesn't give

13:06:06 enough information. It makes me assume that the complication

13:06:12 rate for this device is the same as the previous devices or the predicate device or any other permanent device that I've used. So over time, in using all these devices, you generate sort of a feeling for what the incidence of and the
13:06:29 seriousness of the complications are. By saying it's a known complication in here and not providing a rate, my assumption is that it's the same as all the other filters, and it wasn't.

Q And, Doctor, you continue to implant the Denali filter; correct?

13:06:46 A Yes.

Q And it's got this same language in it, does it not?

A That's correct. But my experience with it is it behaves differently.

MR. ROGERS: All right. Let's move on down to the
13:06:54 next section, please. Not the bullet, but the -- let's go down to section F.

BY MR. ROGERS:

Q And, Doctor, do you see this section?

A Yes.

13:07:08 Q This is known as "Precautions"; correct?

A Yes.

MR. ROGERS: All right. And if we scroll on down, please.

All right. And keep on scrolling, I'm sorry.

13:07:21 All right. Let's move on down past that section and

keep on going, I'm sorry.

There we go. Yeah. Part G, can you pull that out, please.

BY MR. ROGERS:

Q And, Doctor, this is a section called "Potential Complications"; correct?

A It is.

Q And would you agree those first two bullets are the same things that we have reviewed; is that right?

A Correct.

Q And the next bullet says: Perforation or other acute chronic damage of the IVC wall is a potential complication; correct?

A Exactly. Yes.

MR. ROGERS: All right. And scoot down just a little bit.

Keep going. A little more. There you go.

BY MR. ROGERS:

Q And then, Doctor, do you see where it says "filter tilt"?

A Yes.

Q And you agree that that is a disclosed complication; correct?

A This IFU discloses basically every known complication that could occur with an IVC filter and probably almost every device.

13:08:23 Q And, Doctor, are you familiar with the IFU for the G2X?
A Yes.
Q And would you agree with me that the G2X IFU contains the same information?
13:08:33 A Agreed. By having this many warnings and precautions, you basically dilute out any particular warning that could be effective for a physician to use.
Q And so you're critical of this IFU because it provides too much information, in your opinion?
13:08:48 A It dilutes out any warning that it could be important.
Q All right. Doctor, I notice that in your questioning from Mr. O'Connor that you referred to Mrs. Hyde's filter as a G2X filter; is that right?
A That's my understanding, yes.
13:09:04 Q And in your review of the imaging of that filter, would you agree with me that you could not see anything in any of the imaging where you could discern based on that imaging whether the filter was a G2X or an Eclipse filter?
A There is no way to know based on imaging.
13:09:20 Q All right. Thank you, Doctor. I don't have any further questions.

THE COURT: Any redirect?

MR. O'CONNOR: Yes, Your Honor.

11:19:09

R E D I R E C T E X A M I N A T I O N

BY MR. O'CONNOR:

Q Dr. Hurst, let's go back to when you were questioned about the different conditions that Ms. Lisa Hyde suffered from.

13:09:43 Were you asked in this case to look at the relationship between the filter failures that her filter experienced and any symptoms she had?

A No.

Q One of the problems that you pointed out, is it true that

13:09:56 other than interventional radiologist who implanted this, was the rest of the medical community, doctors in different disciplines, aware of the failures that were occurring with Bard filters?

A Not at that time, no.

13:10:08 Q And would doctors who did not practice in interventional radiology have any reason to know whether they should be looking at a filter for -- a Bard filter for potential complication if a patient presented with a certain type of symptom?

13:10:24 A No.

Q And by the way, you understand that there is another expert in our case, Dr. Muehrcke; correct?

A Yes.

Q And he's a cardiovascular surgeon.

13:10:38 A Yes.

13:10:38 Q Have you reviewed his report?
A Yes.
Q And you understand that he is going to talk about causation and the -- the issues with Mrs. Hyde, Lisa Hyde,
13:10:47 from the failures that her filter experienced?
A From a clinical standpoint, yes.
Q And by the way, you were asked questions about asymptomatic. If a Bard filter fractures and migrates anywhere, including the right ventricle, does the fact that
13:11:06 it's not causing symptoms to a patient make it any less serious?
A No. I don't think we know the natural history of having a filter fragment in the right ventricle. We don't know what the potential risks are over time.
13:11:21 I see it as kind of like a -- almost like a needle sitting in a moving structure that is compressing, you know, hundreds and hundreds of times a day. That needle can move, or that arm, fragment, whatever it is, can puncture the heart at any moment. We just don't know the natural history of
13:11:44 these fragments in the heart. So they're potentially very, very dangerous.
Q Now, on your compensation, first of all, does it matter which side you are on when you look at a case?
A No.
13:12:03 Q And why do you do expert work?

13:12:08 A Well, I find the work --

MR. ROGERS: Object. That's been asked and answered.

THE COURT: Overruled.

THE WITNESS: I find the work interesting. Again, I said this before, but I think it makes me a better physician, it makes my practice better. I do it for my patients. And I enjoy the process of helping the attorneys and the jury and everyone understand the medical issues at hand in the case. So I find it very rewarding.

13:12:37 BY MR. O'CONNOR:

Q Do you ever turn down cases?

A Absolutely. I turn them down all the time.

Q For what reasons?

A For insufficient -- well, I turn down because they're bad cases. They're not cases that really -- that I feel that I can either support one way or the other. Either they lack evidence or they seem frivolous.

Q Have you looked at what other doctors in your area charge when they do medical-legal consulting and come and talk to courts and juries?

A Yeah. Actually there's a survey that goes out every year and comes back to me from the S-E-A-K, the SEAK company that lists expected and the average reimbursements.

Q And where do your fees fall?

13:13:29 A I'm a little bit below average to average.

Q And you've reviewed reports from experts that have been retained by Bard.
A Yes.
Q And are they charging that company?
A Yes.
Q And is there much difference between what they have been charging and what you talk about?
A No.
Q Now, just to be clear, on this Denali, you did stop using it for a reason; is that correct?
A I stopped using it as a permanent device.
Q Is it still promoted by Bard and represented as a permanent device?
A Yes, it is.
Q As a matter of fact, every device that we've talked about from Bard, the G2, the G2X, and the Eclipse, were they always represented by Bard to be permanent filters?
A Yes, they were.
Q And in terms of doctor expectations, what did that mean?
A That means that you would expect it to be stable over the lifetime of the patient.
Q Now, you were asked questions about your report and how you listed out 20 to 25 Bard documents.
A Yes.
Q You've been deposed in this case; correct?

13:14:41 A Yes.
Q Have you told the people at Bard before that you've reviewed more?
A Yes.
13:14:48 Q Well, let me ask you a question. Have the attorneys from Bard ever presented a Bard document to you and asked you to look at that and see if it refutes the documents you brought in here and talked about in court today?
A No, they have not.
13:15:03 Q Have they ever came to you and said, you know, Doctor, that HHE you relied on or that G2, G2X fracture analysis, we have something to show you that may change your mind?
A I've never had that happen.
Q Have you welcomed that opportunity?
13:15:17 A I've asked for them. Yes.
Q Now, you were asked questions about the FDA August 9, 2010, recommendation. Do you recall that?
A I do, yes.
MR. O'CONNOR: Was that exhibit put into evidence, 13:15:46 Your Honor? 80 -- 6993?
THE COURT: I don't think so, no.
MR. O'CONNOR: Pardon me?
THE COURT: No.
BY MR. O'CONNOR:
13:15:54 Q In any event, are you aware of what that FDA

communications stated?

A Yes.

Q And what type of filter was it talking about?

A It was talking about all retrievable filters.

Q Retrievable filters?

A Right. Yes.

Q And did it indicate that -- first of all, does the FDA regulate the medical practice, the practice of medicine?

A They do not regulate the -- no. Practice of medicine, they do not.

Q Did Bard ever contact physicians using Bard filters to let those physicians know about the FDA communication?

A No.

Q And did Bard ever do anything to change any of the documents such as these instructions for use based upon the FDA?

A No.

Q In fact, did Bard ever, in any document, any information for use document, ever state that doctors should be monitoring patients who have received Bard filters?

A Not using imaging. And they did not give a time for retrieval. The FDA recommendation that came out in 2010 recommended that implanting physicians and clinicians who were responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection

for PE was no longer needed.

Q And that was retrievable filters.

A That was retrievable filters, yes. So at that point the recommendation was that any device that was in the retrievable category should be removed once the indication or protection from PE was no longer needed.

Q And you were asked questions about the instructions for use, I think it was Exhibit 8325.

MR. O'CONNOR: Could we put that up, please, Felice.

And, Felice, if you could go --

Your Honor, may I display this to the jury? I believe it's in evidence.

THE COURT: You may.

MR. O'CONNOR: Felice, go to what looks like Bates number 3.

Thank you. And then, I don't know -- can you enlarge it just above MRI safety, above that I want you to highlight the section, that paragraph right above MRI Safety, the one right above it.

The one I'm looking at is this paragraph, the last paragraph before MRI safety.

Let me show you --

THE WITNESS: Do we have a better copy?

MR. ROGERS: Your Honor, Mr. O'Connor is welcome to use the document that I used.

13:19:24 MR. O'CONNOR: Could we have that one up. I think ours is worse quality.

Thank you.

It's 8325.

13:19:36 Thank you.

And it was at page 3. And the paragraph right above "MRI Safety."

Could you highlight -- there you go.

BY MR. O'CONNOR:

13:19:53 Q Now, this is the Eclipse instructions for use; correct?

A Yes.

Q And does this indicate that Bard continued to represent and promote its filter, the Eclipse, as well as the G2X, as a permanent filter?

13:20:11 A Yes.

MR. O'CONNOR: And then if we could go to the "Warning" section, subparagraph 8, please.

BY MR. O'CONNOR:

Q What I wanted you to look at, Dr. Hurst, when did the 13:20:45 Eclipse filter start coming out into the market?

A Was it 2008? I think.

Q Eclipse was closer to 2010. Does that sound right?

A 2010. Sorry. August 2010. So 8/2010. Yes.

Q So you have looked at all of the instructions for use; 13:21:05 correct?

13:21:06 A Yes.
Q Number 1, if you look at this, it says under section 8: "There have been some reports of serious pulmonary and cardiac complications with the vena cava."
13:21:18 Do you see that?
A Yes.
Q Now, did you learn from looking at Bard internal documents that the complications that you saw and what Bard was aware of was more than just some reports?
13:21:33 A Yes. Yeah. And on top of that, I mean, this particular complication can be catastrophic. I mean, this is almost -- should be like a black box warning, not just --
MR. ROGERS: Objection, Your Honor. This is beyond his report and expertise.
13:21:54 MR. O'CONNOR: He was asked about this very paragraph and on these very issues on cross-examination.
THE COURT: Well, let's approach for a minute, Counsel.
You can stand up, ladies and gentlemen.
13:22:03 (Bench conference as follows:)
THE COURT: Where are you going with this, Counsel? How far are you going to go?
MR. O'CONNOR: Just wanted him to explain his opinion that these warnings that they brought up are inadequate and
13:22:31 the reason why is they don't spell out what he knows about as

13:22:34 adverse events. And also that Lisa Hyde's complication is a serious catastrophic complication, not just something that's been reported.

THE COURT: Okay.

13:22:46 MR. ROGERS: Your Honor, he just testified that this should have been a black box warning. It's clearly a regulatory opinion. Not disclosed in his report. He's not qualified to talk about it.

THE COURT: Well, do you agree that it's fair game 13:22:59 for them to ask him why he doesn't think this warning is adequate since you introduced --

MR. ROGERS: I completely do, Your Honor. I agree with that.

THE COURT: It's the black box --

13:23:11 MR. ROGERS: He's just starting to slide into areas he's not an expert in or not disclosed.

THE COURT: I don't think the jury has any idea what a black box warning is.

MR. ROGERS: I don't think they do.

13:23:20 THE COURT: I don't think they know it's an FDA matter, so I don't think we need to go back and correct that. Do you agree?

MR. ROGERS: I'm fine with that, You're Honor.

THE COURT: I think going forward it's fair game. 13:23:28 But obviously you should steer him away from FDA opinions if

13:23:31 he ventures --

THE COURT REPORTER: Excuse me. I can't hear.

THE COURT: She can't hear you.

MR. LOPEZ: A black box warning is not an FDA issue.
13:23:45 A black box warning is a company issue and whether or not the warnings on the label are prominent enough and adequate enough to put doctors on notice of a serious complication.

THE COURT: Do you --

MR. LOPEZ: He's familiar with what a black box
13:23:58 warning means.

THE COURT: Have you disclosed him as a witness who could testify about what should or should not be a black box warning?

MR. LOPEZ: We didn't intend to until he started
13:24:06 cross-examining him on --

THE COURT: I think he -- I think you can fairly redirect him on why he thinks this is inadequate without him starting to give opinions on black box warnings.

MR. LOPEZ: Okay. I mean, I respectfully disagree,
13:24:18 Judge. He needs to go to the extent of what his opinion is. If his opinion as a physician is that it's such a catastrophic injury that we're talking about here that involved these -- for a physician to really see it, it --

THE COURT: Okay --

13:24:35 MR. LOPEZ: You can't just --

THE COURT: -- you can disagree with me, that's okay.

MR. LOPEZ: I know. But, you know --

THE COURT: No, my point is this is fair game for cross, but if he's venturing into things like there are certain categories of warnings that the company should have given, that's beyond explaining why he thinks the language that's called to his attention was not sufficient.

MR. LOPEZ: Okay. I mean --

THE COURT: So I think it's fair game to go into it but stay away from those sorts of affirmative opinions.

MR. ROGERS: Thank you, Your Honor.

(Bench conference concludes.)

THE COURT: Thank you all.

MR. O'CONNOR: May I resume, Your Honor?

THE COURT: Yes.

BY MR. O'CONNOR:

Q Dr. Hurst, you've reviewed these instructions for use; correct?

A Yes.

Q And I think you told us it's your opinion that these instructions for use do not adequately provide information to physicians like you about the complications that Bard was aware of its filters.

A Right. The comp- -- the -- instructions for use should be clear and accurate and consistent. The Bard Eclipse IFU lists

over 20, maybe 25 potential complications, and then you saw a laundry list of every possible complication that could occur without giving you an idea of which ones you should really be worried about.

This number 8 that we're looking at here would be one that I would highlight if I -- I would want to know that this is a severe, significant, issue that is occurring with this filter that is not occurring with other filters and that I should look out for it.

Q As we saw, Bard did an internal analysis of fractures comparing the G2 and the G2X with other filter; correct? Do you recall that?

A Yes.

Q And when you saw that, did you -- is it your opinion that that is the type of information Bard should have provided to physicians and physicians should have reasonably expected Bard to disclose that information?

A In some shape or form, yes.

Q And was it?

A No.

Q And in terms of Bard filters, you talked about on cross that the issues with Bard is that the Bard filters experienced more than one or -- complication; is that correct?

A Yes. They experienced almost all of them.

Q And in Lisa Hyde's case, is her case a case where her

filter engaged in more than one failure mode?

A It definitely had penetration and it definitely fractured, with migration of the fracture fragment.

Q And did you attribute those to the insufficient stability of Bard filters?

A I attribute it to the design of the Bard filter, yes.

Q The instability part of it?

A Yes. Right.

Q Did Bard represent its filters as having strength and stability?

A Yes.

Q Did Lisa Hyde's filter prove to live up to that representation by Bard?

A No.

Q Now, you were asked questions about the SIR guidelines and trackable events. Can you just tell us what those are.

A The SIR guidelines were created to allow -- I'm sorry, they were created as guidelines for hospitals and interventional radiology departments to use for quality assurance to identify when complications or issues regarding devices or procedures fall out of sort of an agreed upon benchmark so that you can have basically a quality assurance program.

Q And whether a filter has a trackable event or not, when it fails, it can cause injury and risk of harm to patients;

13:29:07 correct?
A Yes.
Q And in terms -- you had said on cross-examination, you said that Lisa Hyde experienced a catastrophic event?
13:29:15 A I would consider a filter migration of a fragment to the heart catastrophic, yes. Or potentially catastrophic.
Q And the reason?
A It's going to require intervention of some sort. Either surgery or a complex endovascular technique that has high
13:29:30 risk.
Q And did Bard ever talk to physicians about its filters that they were aware those filters posed a risk of catastrophic events as opposed to some failure modes?
A No, they never used that language.
13:29:43 Q Would that be something physicians should reasonably expect from medical device company like Bard?
A Yes.
Q And Bard filters were, as we said, the G2, the G2X, were promoted and represented as permanent filters with the option
13:30:08 to retrieve. When they talked about retrieval, what type of procedure were they talking -- Bard talking about? Percutaneous?
A Yes.
Q Meaning what?
13:30:19 A Usually you place a small sheath through the internal

13:30:23 jugular vein of the neck. Under X-ray guidance, you guide that sheath down to the position just above the filter, and then you take either a grasping device or a lasso if it has a hook and you grab it and pull it up into the sheath, just like 13:30:41 would you take a umbrella and take your hand and just close it like that, and then you pull it out of the patient.

Q Now, Lisa Hyde underwent a complex procedure; is that correct?

A Her removal of her filter as was shown did not appear to 13:30:55 be complex. There were no fragments that occurred during the removal. It seems like they were able to retrieve the device that was in her inferior vena cava pretty straightforward.

The fact, though, that she had to have a procedure, the second part of the procedure where they guided that sheath 13:31:14 that I'm talking about into her heart and then attempted to retrieve a -- basically a needle from her heart that was actively beating with a lasso, it's pretty impressive how quickly he got it out and, you know, she did not have any complications. But you can have tremendous complications 13:31:35 trying to remove these fragments.

Q And you're not here to talk about what issues she may have from having a procedure to her heart. Fair?

A I'm not here to talk about that.

Q But is it fair to say, Dr. Hurst, that when doctors like 13:31:49 you were implanting these filters, is it fair to say that

neither you as the doctors nor the patients ever had any expectation or should have reasonably expected that the filter would break, embolize, land in the ventricle, and then require a procedure, and possibly an open procedure?

MR. ROGERS: Objection, Your Honor, to the portion of the question where he's addressing what patients would have known.

THE COURT: Overruled.

THE WITNESS: So no, that's not what we expected. And, in fact, I was discussing this with someone that when you have that clinic visit, that is a terrible clinic visit when you have to talk to a patient about a device that's failed. And fortunately I have not had one that has failed where the patient has had to have some sort of cardiac procedure to remove it.

But, you know, explaining to a patient that their device that you put in has broken and a piece of it has gone into their heart and now they're going to have to have some sort of cardiac procedure is a really big deal. It's a pretty quiet room when you're having that discussion.

Q Bard, did they ever alert physicians to be on the lookout for catastrophic events?

A No.

MR. O'CONNOR: That's all I have. Thank you.

THE COURT: Thank you. You can step down, sir.

MR. LOPEZ: Your Honor, plaintiffs will call Dr. Michael Streiff.

MICHAEL STREIFF, M.D.,

called as a witness herein, after having been first duly sworn or affirmed, was examined and testified as follows:

MR. LOPEZ: May I proceed, Your Honor?

THE COURT: You may.

MR. LOPEZ: Thank you.

D I R E C T E X A M I N A T I O N

BY MR. LOPEZ:

Q Good afternoon, Dr. Streiff. Thank you for being patient. I know you've been here since the morning.

Would you please introduce yourself to the members of the jury.

A Certainly. So I'm Michael Streiff. I'm a hematologist, so a doctor that takes care of people with blood diseases. And I did my training in the early 1990s, have been on staff at Hopkins since 1997 as a hematologist. Primarily I focus on diseases which involve blood clots or bleeding disorders, so people that have developed DVT or pulmonary embolism or have diseases that increase your risk of having a blood clot or diseases that cause bleeding problems. That makes up probably 65 to 70 percent of the patients I see on a daily basis.

Q And a hematologist, what are the types of patients -- I know you mentioned some, but what is your basic patient

13:35:49 population that you see as a hematologist?
A So if you look at all the patients I see, I'd say all of them, almost all of them, 95 percent of the patients I see have benign blood diseases. So there are malignant blood
13:36:06 diseases like leukemia, lymphoma, myeloma. I tend not to see very many of those patients. There are other specialists at our center that I would ref- -- if I were to happen to make a diagnosis of someone with one of those diseases, I refer them to because there are doctors that specialize in that type of
13:36:23 blood disease. So I focus primarily on benign blood diseases. So bleeding, clotting, diseases of anemia, sickle cell anemia, low platelets, high or low white blood cell counts.
Q Do you make -- you make therapeutic decisions on behalf of those patients that might include pharmaceuticals or medical
13:36:43 devices?
A Certainly, yes. Yes.
Q And among those methods of treating those patients, have you had in your experience as a hematologist patients who have had IVC filters?
13:36:58 A Yes. Certainly. I think any hematologist that sees -- practically any hematologist, but I'd say any hematologist who sees a bulk of patients that have blood clotting diseases, you're going to have patients that you have to make that decision. And we get -- I'm on service every month of the
13:37:16 year, and I'd say that every month I'm on, we get asked about

13:37:20 a patient that had has a blood clot where they're having difficulty treating it, and so then you have -- a filter would be one of the things you would consider in that case.

Q Now, I -- we've heard anticoagulants or anticoagulation 13:37:34 therapy already in this trial. Is that a method of treatment for this type of patient that you've studied and that you've used that type of medication with this patient population?

A Certainly. So one of my roles at Hopkins is I run an anticoagulation clinic. So we have a clinic in our cancer 13:37:56 center and then a clinic over on the -- where we have patients that don't have cancer that go too that also need blood thinners or -- which is kind of a common parlance for an anticoagulant, and I have a staff of pharmacists that manage warfarin, but they also help manage other blood thinners, 13:38:12 injectable blood thinners like loma- -- heparin or some of the new drugs that are on the market now that you don't need to monitor. So I see lots of patients that are on an anticoagulant for treating blood clots or preventing another blood clot from happening.

13:38:30 Q Have you also studied and written articles regarding IVC filters and the potential use of those devices to treat that patient population?

A Certainly. So early on in my training when I was a fellow, my mentor, Dr. Bell, who I think occupied a similar 13:38:47 clinical niche to me, had very certain ideas about vena caval

filters and was very vocal about it.

But I thought -- as a fellow, I thought, well, I really want to know what the literature is behind these devices because they were -- this is before we had retrievable filters. In the 1990s they were all permanent filters. But I wanted to know what was the literature behind why -- you know, why was he so negative about vena caval filters and was he being balanced about this view of filters.

And so one of the first papers I wrote was doing a comprehensive review of the literature. I published this in 2000 in Blood. Of all of the clinical studies that had been done at that point on vena caval filters, because I wanted to make up my own mind. I wasn't just going to -- although Dr. Bell was a very, very knowledgeable physician --

MR. CONDO: Your Honor, I would object to any hearsay offered through this witness about Dr. Bell's views or points of view.

THE COURT: Sustained. I think this is just background, but going forward obviously it is just Dr. Streiff's opinions that are --

BY MR. LOPEZ:

Q Now, sir, I'm not going to walk you through all of the different articles and things you've written as they relate to IVC filters, but I'm going to ask you about a couple.

Do you know a Dr. John Kaufman?

13:40:13 A John Hoffman.
Q No, Kaufman.
A Kaufman. Yes. Of course. Yes. I've worked with him on several papers, yes --
13:40:19 Q And did you write an article --
A -- radiologist.
Q I'm sorry. Did you write an article with Dr. Kaufman that was published in the Society of Interventional Radiology Journal in 2006 entitled "Guidelines for Use of Retrievable
13:40:34 and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference"?
A Yes, sir. He reached out to me in 2005 and asked me to be part of that meeting that they had after a conference in Miami
13:40:51 Beach that year.
Q Okay. Now let's fast-forward to the present. Are you still writing significant authoritative articles, text chapters that deal with the use of IVC filters?
A Certainly it's still one of my -- it was one of my early
13:41:08 interests in hematology and I still keep an eye on the literature there. I -- I'd say I spent a lot more time on anticoagulant therapy and optimizing that, but I do, you know, continue to write articles on that. And we just, a colleague of mine, Anita Rajasekhar, and I published a chapter that just
13:41:32 came out the last month in a textbook of thrombosis and

13:41:36 hemostasis, which is a textbook for people that treat blood clots.

Q Is that a chapter devoted to IVC filters?

A Yes. IVC filters and venous access devices, so catheters

13:41:47 that you can put medicines into.

Q We'll get back to this, but you actually have a certain patient population recommend and prescribe IVC filters. True?

A Certainly. I think that I -- I consider filters in patients where you can't use anticoagulants. And,

13:42:07 fortunately, that's a small segment of the patient population that has blood clots. But occasionally people, right after major surgery, neurosurgery, and they're not -- it wouldn't be safe to use a blood thinning medication in that situation. You would have -- could have a catastrophic bleed. And so

13:42:26 those patients are patients that we would consider -- I would consider using a filter. If they have a blood clot that would put them at risk for the pulmonary embolism, then you have to do something to prevent that from happening.

Q Now, you've been retained in this case to serve as an

13:42:38 expert on behalf of the plaintiffs. True?

A Yes.

Q And what is it that we asked that you address for purposes of your role here as an expert?

A So you asked me to, because I keep my eye on the

13:42:55 literature, to look at the literature that supports the use of

13:42:58 vena cava filters and indications for a vena cava filter based on the literature. So an evidence-based review of it. And also what would I, as a physician that refers patients to interventional radiologist like Dr. Hurst, who just spoke, I
13:43:18 make referrals to those physicians for filter placement, and what knowledge, what information would I want from manufacturers of filters to make a good evidence-based judgment and give my best advice to patients, because that's what you want to do is you want to, here are the risks we're
13:43:36 facing for using a blood thinner, here are the risks with a filter, and you want to know all of the information that relates to the risk/benefit balance.

Q Now, Doctor, I'm going to -- I think one of the other things that we asked you to do is to look at some of the
13:43:51 scientific evidence and medical evidence that exists to -- to give what you would consider a risk/benefit assessment in prescribing these --

MR. CONDO: Objection. Leading.

THE COURT: Overruled. This is background.

13:44:06 BY MR. LOPEZ:

Q -- in the use of these filters?

A Certainly. So with filters, the things you get concerned about, as we've heard earlier today, are, are they stable? Are they going to remain at the location where they're
13:44:21 implanted? They're supposed to operate as a barrier to a clot

13:44:24 moving from the legs to the lungs, which could be a fatal event, and so there's supposed to be a stable barrier there. They're not supposed to move, they're not supposed to fragment. The legs, which keep them anchored in that location 13:44:37 are not supposed to perforate the vessel that they're in and enter into other organs where they could cause problems. And so you'd want the information about how often does that occur with this device versus this other device versus -- to make a judgments.

13:44:54 Q Doctor, describe -- there are certain ways that medical devices can be studied to determine whether or not they're safe, whether they're effective. Let's talk about the effectiveness of these devices. What kind of studies have been done to determine whether or not IVC filters do what 13:45:13 they're represented and intended to do?

A So that -- unfortunately haven't been -- although there are lots and lots of studies, if you happen to do a Google search or a PubMed search for the vena cava filter, you'll see thousands of articles out there, including a few that I've 13:45:29 written, but thousands and thousands of articles.

But actually only really two randomized trials that have been published regarding vena caval filters, and that is when you -- if there's a hierarchy of the medical literature, randomized trials are at the top of that hierarchy because in 13:45:48 a randomized trial, the investigators blindly sort. You know,

13:45:52 they have their certain pool of patients that could participate in this study. You present the risks and benefits of participating, and then people are randomly sorted toward one treatment or another, and the investigators don't choose 13:46:06 who gets what treatment. So you then get an unbiased view, a relatively unbiased view, of what the risks and benefits and the efficacy of that device or that drug is.

And the highest -- I guess in the hierarchy, the best randomized control trials are blinded trials where neither the 13:46:26 patient nor the investigator know what intervention they're getting. There's two studies that have been done in -- with vena caval filters, both in Europe, were open trials. So the doctors knew who got the filters. The patients of course knew who got the filters. It would be hard to do a study with -- 13:46:44 pretty hard to do a study without telling them. And so it's not the best level of evidence, but it's the best we have.

For the other 8,000 studies that are out there, there are lesser degrees of quality where people have looked back at past practice and kind of see what happens with filters or 13:47:03 have had a prospective, in other words, they follow people forward in time to see what happens with filters, but there's no random assortment into one treatment or another.

Q Okay. We're actually getting into those. You're used to teaching, aren't you?

13:47:19 A Yeah. Sorry.

Q All right.
A Talk a lot. Yeah.
Q So let me ask this: Has Bard ever conducted a randomized clinical trial of their filters to determine whether or not they actually do what they're intended to do? That is, to prevent fatal pulmonary embolism?
A No. Not to my knowledge.
Q And the two studies you're talking about, did they look at IVC filters to determine whether or not in the two groups that were being studied, whether or not the folks in the filter group actually had a better result from the standpoint of mortality or causing fatalities than the group that did not have filters?
A So in both those studies that I've referred to, there was no difference in mortality between the people that didn't get a filter and the people that did get a filter. Now, everybody got anticoagulants or blood thinners in those studies, so you were adding up -- in half the patients you were adding a filter on top of anticoagulation.
Q Just so we're clear, the only two studies that exist that would be considered as high level randomized control study that compares whether or not filters actually do what they are intended to do, or maybe not do, are these two studies you're talking about?
A Yes, sir. Yeah.

13:48:45 MR. LOPEZ: And could we have Exhibit 3709, please.
BY MR. LOPEZ:
Q And it should come up on your screen.
A Do I have to do anything --
13:49:02 THE COURT: No.
THE WITNESS: Oh, yeah, I see it. Yes.
MR. LOPEZ: 3709.
THE WITNESS: Yeah. That looks like it.
MR. LOPEZ: Oh, okay, yours is in color.
13:49:14 BY MR. LOPEZ:
Q All right. So this is the -- is this that first study that you talked about where they did a randomized control study?
A Yes, sir. This is the eight-year follow-up of that first
13:49:23 study.
MR. LOPEZ: And, Your Honor, I know we can't show this to the jury, but can I publish the title to the jury?
THE COURT: You can have him state the title.
MR. LOPEZ: Okay.
13:49:31 THE COURT: If it's not in evidence, you can't show it.
BY MR. LOPEZ:
Q And this is published in an authoritative journal?
A Yes, sir, in Circulation.
13:49:40 Q In a journal that's a reputable journal that's read by

13:49:44 physicians like yourself?

A Yes, sir.

Q Could you read the title of this article to the jury, please.

13:49:53 A So the title is "Eight-Year Follow-Up of Patients with Permanent Vena Cava Filters in the Prevention of Pulmonary Embolism: The PREPIC", that's an abbreviation for a number of words in French --

Q You don't have to read the French.

13:50:11 A -- "Randomized Study."

Q Let's go to the next page, and explain to the jury again the randomized part of the study, but who was in one group and who was in the other group.

A So the investigators had a -- at the I guess central 13:50:31 center where the study was being coordinated from would send random -- they would generate random numbers that would -- if you had a patient that said, yeah, I'd like to participate in this study, I have a blood clot and I would like to be involved in this study, then the central center that was 13:50:47 coordinating the study, they have a random number generator that would tell the physicians that are working in that medical center, because it was in many, many different medical centers, would tell them whether that patient was going to get a filter or not. So it randomly chosen. Kind like randomly 13:51:02 out of a hat. They were told whether or not this patient

would receive a filter or not.

All of the patients were already started on blood thinners for their blood clot. The patients all had a pulmonary embolism and were felt to be at high risk for having another, which is why they were chosen.

Q Okay. Doctor, this was in 2005?

A This paper came out in 2005, yes.

Q And there under "Background," would you please read the last sentence to the jury under "Background."

A "An eight-year follow-up was performed to assess their very long term effects. The filters" --

Q Okay. So this was an eight-year follow-up to look at the long-term effects of the effectiveness of IVC filters?

A Yes.

Q Okay. And the conclusion, could you read that to the jury, please.

A Sure. "At eight years, vena cava filters reduced the risk of pulmonary embolism but increased the risk -- or increased that of deep vein thrombosis and had no effect on survival. Although their use may be beneficial in patients at high risk of pulmonary embolism, systematic use in the general population with venous thromboembolism," another term for deep vein thrombosis and pulmonary embolism, "is not recommended."

Q Now, when it said -- when the conclusion of this study reads "that there is no effect on survival," what does that

mean?
A It means that the survival rates in both arms of the study were similar.
Q And then was there a later study similar to this one where there was a follow-up with a similar patient population?
A Yes. You'd be referring to the PREPIC, the second in a series of studies, the second PREPIC trial that looked at retrievable --
Q Hold on. Hold on. Slow down.
A Oh, I'm sorry.
MR. LOPEZ: We're going to bring up Exhibit 4147.
BY MR. LOPEZ:
Q Okay. Do you see that? Do you have that in front of you, Doctor?
A Yeah.
Q And this was published in what journal?
A This was published in the Journal of the American Medical Association known as JAMA.
Q Okay. And that is an authoritative journal, well-recognized, peer-reviewed?
A Yes. It's very well respected.
Q And this was in 2015?
A Yes, sir.
Q So this is at a time after retrievable filters had been on the market for a while; right?

13:53:30 A Yes, sir.
Q In fact, this is a retrievable filter study, is it not?
MR. CONDO: Your Honor, I'm going to objection to leading the --
13:53:39 THE COURT: I'm going to sustain that. It's clearly leading.
BY MR. LOPEZ:
Q Is this a retrievable filter study?
A Yes, sir. This is a retrievable filter study because by
13:53:44 this time there was -- by the time this study was starting -- started up in 2006, there was a lot of interest in testing whether retrievable filters, whether they would behave differently than the permanent devices that had been on the market.
13:53:59 Q Maybe I should have just read you -- had you read the title of this article. Will you do that?
A "The Effect of a Retrievable Inferior Vena Cava Filter Plus Anticoagulation vs Anticoagulation Alone on the Risk of Recurrent Pulmonary Embolism. A Randomized Clinical Trial."
13:54:19 Q So you're familiar with the Bard G2, Recovery, G2X, Eclipse filters. Those would be considered retrievable filters; correct?
A Yes, sir.
Q Would you please read the "Importance" portion of the
13:54:35 front page of this article.

13:54:39 A It states: "Although retrievable vena cava filters are frequently used in addition to anticoagulation in patients withs acute venous thromboembolism, their benefit-risk ratio is unclear."

13:54:53 Q And what was the objective of this randomized control study?

A To demonstrate that if you used the vena cava filter in addition to anticoagulation, you would decrease the risk of pulmonary embolism because you'd be -- in addition to

13:55:08 anticoagulation be placing a physical barrier to clots transmitting to the lungs and that that might have an output. You know, decrease pulmonary embolism, decrease death rates due to pulmonary embolism.

Q And just read the first paragraph, Doctor, if you will,

13:55:23 under "Design Setting and Participants."

A "Randomized open-label blinded end point trial." So that means that it was everybody -- you know, doctors and patients both knew if they got a filter or not or if they just got anticoagulation.

13:55:40 And then the outcomes that happened, if you happen to have another episode of chest pain that turned out to be a pulmonary embolism, that was adjudicated by a group of investigators that had nothing to do with the study and wouldn't know which arm of the study the patient was on. So

13:55:58 they were blinded as to what treatment the patient got. They

would just judge, yes, that is a pulmonary embolism or no, that's not a pulmonary embolism, based on the images and data that they were given. So they were blinded to what group the patients were in.

Q And, again, between 2005 and 2015, did Bard or any other IVC filter manufacturer sponsor a clinical trial like this?

A No, sir.

Q Are there any other clinical trials like this published in the world literature?

A There are no other randomized control trials like this.

Q There are some other types of trials that are maybe lower -- like retrospective, is that what those are called?

A Yeah. Retrospective or prospective single arm studies where there is no comparator.

Q Now, in the last -- since 2015, now we're in 2018, have there been other articles written in the medical literature that looked at whether or not filters save lives?

A I think there have been articles that looked at -- so there have been articles that look at large populations of patients that, if you have access to, like, Medicare or Medicaid data, you can look at thousands and thousands of patients and see based -- see people that got filters and did not get filters, and then look and see how they did by just looking at in kind of a blinded fashion at the medical records. So those kind of studies, but those are not

13:57:26 randomized studies.

That's where you're following what doctors did and therefore it's -- because doctors may place filters in one type of patient and not in another type of patient. It's not 13:57:37 like a randomized trial.

Q I understand. But it's still physicians -- is it still physicians looking at outcomes to see whether or not there is any evidence that IVC filters actually reduce the risk of fatal pulmonary embolism?

13:57:53 A True. That they've done studies like that.

Q Let's turn back to Exhibit 4147.

MR. LOPEZ: Your Honor, I understand if he's reading it I can't publish what's what he's reading to the jury.

THE COURT: It's not in evidence.

13:58:08 BY MR. LOPEZ:

Q So under the "Design Settings and Participants," I wanted you to point out that first sentence about the six-month follow-up. Can you read that to the jury and explain what that means.

13:58:22 A So I --

Q Read the sentence first?

A Yeah. "Randomized open-label, blinded end point trial," so I did that before, "with 6-month follow-up conducted from August 2006 to January 2013."

13:58:35 Q Okay. And then let's go right to the "Results." Okay?

13:58:40 And could you read that first paragraph of the "Results."
A So, "In the filter group, the filter was successfully inserted in 193 patients and was retrieved as planned in 153 of the 164 patients in whom retrieval was attempted. By 3
13:59:01 months, recurrent pulmonary embolism had occurred in 6 patients, 3.0 percent; all fatal, in the filter group and in 3 patients in the control group, 1.5 percent; 2 fatal."
Q Keep reading.
A So the relative risk with the filter for the outcome of
13:59:22 pulmonary embolism was 2.0. So that means there's twice as likely to occur in the filter group as the nonfilter group, but there's some statistics that follow that basically suggest that although it's twice as likely, it's not significant because it's a very -- they're very small numbers of patients
13:59:41 that had that outcome, fortunately.
And the "results were similar at 6 months. No difference was observed between the 2 groups in regards to the other outcomes." And "filter thrombosis occurred in 3 patients."
13:59:57 I think the other outcomes were death, deep vein thrombosis, are the ones that come to mind.
MR. LOPEZ: I'd like to move 4147 into evidence.
MR. CONDO: Your Honor, he may have established --
THE COURT: What's the objection?
14:00:19 MR. CONDO: Hearsay.

14:00:21 THE COURT: What's your response on hearsay?

MR. LOPEZ: This is a -- one of two articles --

THE COURT: Is it --

MR. LOPEZ: -- that goes to notice.

14:00:32 THE COURT: -- learned treatise under 803(18)?

MR. LOPEZ: Yes, Your Honor, learned treatise.

THE COURT: Denied. 803(18) specifically says the exhibit is not shown to the jury.

MR. LOPEZ: I understand, but the exception would be 14:00:43 notice to Bard about articles that are being written that they monitor and read for purposes --

THE COURT: Are you saying you want it admitted not for the truth of what's in the article? That's what you're saying if you're making a notice argument.

14:00:59 MR. LOPEZ: Well, I mean, if it doesn't come in, it's not coming in that way anyway.

THE COURT: Well, he can read it under 803(18) but the exhibit isn't shown to the jury under 803(18).

MR. LOPEZ: All right.

14:01:10 BY MR. LOPEZ:

Q So let's go back to the "Results" section, and I want to make sure we're clear about what you read there.

In the filter group there were three patients that died from a pulmonary embolism; right?

14:01:28 A There were six patients that --

14:01:30 Q I'm sorry --
A -- died of pulmonary embolism. 3 percent since it was 200 patients in the filter arm.
Q So 3 percent of the patients who received the filter died
14:01:43 of recurrent pulmonary embolism?
A Yes, sir.
Q And in the nonfilter group, three patients or 1.5 percent died of a recurrent pulmonary embolism; correct?
A Yes. Three patients had a pulmonary embolism and two of
14:01:57 those three died. So --
Q So 3 percent --
A I guess 1 percent fatal pulmonary embolism rate.
Q 3 percent of the patients that had a filter had died of recurrent pulmonary embolism. Is that what that says?
14:02:14 A Yes, sir, on the filter --
Q And 1.5 percent, half as many, died of recurrent pulmonary embolism in the control group.
A Or -- yeah. 1.5 percent had a pulmonary embolism and 1 percent or two of those patients, died of their pulmonary
14:02:28 embolism. Two of the three.
Q Have there been any other randomized controlled clinical trials that look at this -- these same kind of outcomes since PREPIC-2 which was published in 2015?
A Not -- they're not of this size. I mean, they're small
14:02:50 trials -- there's a small randomized trial in trauma patients

but it's such a small trial you really can't look at these type of outcomes.

Q What is the current state of the medical evidence with respect to the benefits or the effectiveness of IVC filters?

A Well, I think as a result of this article and the previous study, it's been evolving, I would say, since the late 1990s through to today, such that I think physicians -- or I would say -- I should probably just speak as a hematologist. That hematologists would generally reserve filters, placing or referring a patient to an interventional radiologist or vascular surgeon to place a filter in someone where anticoagulation is not possible because there are concerns about device flaws and bad outcomes with placing filters, and so we only use them now in patients that you can't use your first line therapy, which is anticoagulation.

Q Because of the -- what you just told us about, the current state of scientific evidence regarding the benefits or the effectiveness of IVC filters, do you have an opinion as to the tolerance of risks that physicians and patients should accept when they might need an IVC filter?

A Yes. I would think tolerance for risk would be very, very low. You don't -- because we don't think they have major benefits except for a very small patient population. You only want to place them in a small group of people, people that you can't anticoagulate. And then you would want to place the

safest filter possible because we do know these have -- the devices have side effects.

Q How can product manufacturers, device manufacturers, help you in determining whether or not the risk for their device is acceptable to you as a hematologist?

A Well, I think just similar to what you expect from drug companies that manufacture anticoagulants. If you're using an anticoagulant, you want that compared to the -- whatever is out there on the market, whatever the gold standard is. You want that and you'd want to have in a randomized trial, and you wouldn't accept less. And then you'd want the results of that randomized trial completely transparently out in the medical literature and in their product's labels so that you can make a comparison when you're deciding on drug X versus drug Y. And in this case, you would be deciding on device X versus device Y. And you would want to know head to head how those devices compare to each other.

Q Doctor, let me ask you this. Let's assume -- we know that those studies don't exist. So let's assume that a company has collected clinical data about the complications or the risks of their devices and they've compared those rates and risks to other devices on the market, and their own internal analysis shows their devices are more dangerous than other devices. Is that the kind of information you would expect to be told by that product manufacturer?

14:06:22 A Of course. I think it's incumbent on manufacturers of all products that if you have knowledge that your product may not be as good as another product on the market, you need to make everybody aware that's potentially using your product so that 14:06:37 they can make the right judgments on whether or not you want to use it.

Because as a physician, as a patient, you want to know all of the information about any decision you make for your health.

14:06:50 Q Yeah. Let's assume that a product manufacturer of these devices had -- and they do a risk analysis to determine whether or not a design of a new device is performing in a manner in which they expected or intended it to perform, and the risk analysis from the data that they've collected 14:07:11 determined that there is an unacceptable risk of serious harm because of the design of that new device. Is that the kind of information that you expect companies to pass on to you so you can pass it on to your patients?

A Certainly. You want to make everybody aware of it, all 14:07:27 physicians that are placing these devices are using this drug. And remove it from the market if it's serious enough. I mean, I think it depends on the severity, but you want that -- everyone to be well aware of it.

Q What if the information that's being collected by the 14:07:43 company shows something different than what physicians are

used to with respect to, say, the risk of fracture with this device because instead of the fracture staying close to the filter, they now have multiple cases of that fragment migrating to the heart or lungs or even to other parts of the body. Is that the kind of information you'd expect a company to reveal to you?

A Of course. It's incumbent, I think, upon manufacturers of any device that you make everyone aware that -- of what the flaws are of that device so that they can make the proper decision when treating their patients.

Q Now, you've been involved with patients that have IVC filters going back to at least 2000, I think?

A Yes, sir.

Q You wrote an article in 2000.

A Yes, sir.

Q You used Bard filters in the past?

A I know our hospital has used Bard filters in the past, yes.

Q Have you ever met with Bard representatives to have discussions with them about their devices?

A I think --

MR. CONDO: Your Honor, I would object. This is a disclosure issue. Exceeds the scope of the expert designation.

THE COURT: Is it in the report?

14:08:49 MR. LOPEZ: No, Your Honor.

THE COURT: Sustained.

BY MR. LOPEZ:

Q Let's assume that Bard -- assuming Bard knew that they had
14:09:01 a filter and they knew that the design of the filter was not allowing it to perform in the manner in which they were representing it was performing, what would your expectations be of Bard under those circumstances?

A To remove the device from the market and repair the
14:09:21 defects --

MR. CONDO: Object, Your Honor. This goes beyond the scope of the report too.

THE COURT: Is that in the report?

MR. LOPEZ: No, Your Honor.

14:09:30 THE COURT: Pardon?

MR. LOPEZ: Well, this specific testimony isn't, but the -- it's -- it's his general subject matter he's testifying to.

THE COURT: Objection sustained.

14:09:44 BY MR. LOPEZ:

Q Just give us -- the jury your opinion. In order -- in order for you to do an appropriate risk/benefit analysis with respect to the use of IVC filters, what are your expectations of manufacturers providing you with information about that
14:10:08 performance about those design issues?

14:10:11 A So it's -- as it's alluded to before that if you -- let's say you have a patient that you can't anticoagulate that's after surgery, you're considering a filter. You'd want to know what the success rate of that filter is; how many 14:10:27 pulmonary emboli. They have -- placed in patients that have that device placed. And you'd also want to know the side effects of the device. How often does it fracture, how often do the legs go through the wall of the vessel, how often does it migrate.

14:10:45 You'd want to know all about that so that you can make a good -- an educated decision for your patient, or at least give your patient advice on this device, that's the -- this is the behavior profile of that device and this other one has these results, and maybe this one we should consider 14:11:04 better than this one because of the outcomes.

Q What needs to be done, Doctor, in your opinion, to affirmatively answer the question do IVC filters actually save people from fatal pulmonary embolism?

A So ideally you would have a trial where you had patient -- 14:11:25 the patient population that require a filter, and you would compare them to patients that -- you know, in a randomized fashion, compare them to patients that didn't get a filter so you could prove that filters were efficacious in preventing pulmonary embolism.

14:11:44 I think you couldn't -- obviously couldn't do a study

where you're not giving people any treatment at all, and so I think you'd have to prove it in another way. Maybe in people that were at risk for DVT and PE who were getting preventive treatment, didn't have one yet, and then do a study there where you're looking for -- looking for pulmonary emboli and show that the device reduced the number pulmonary emboli.

Q And that hasn't been done yet; right?

A No.

Q Do you know if anyone's in the process of sponsoring such a study?

A No. I know that a colleague of mine, Anita Rajasekhar, looked in a population, in the trauma population. So people with who had a major trauma, motor vehicle accidents, are at a very high risk for blood clots, very high risk for pulmonary embolism. They did a small study at the University of Florida where they had everyone on preventative -- kind of preventative blood thinners but not full-dose anticoagulation, and then randomized them to get filters or not get filters. But it was a very small study to show its potential to be done, that type of study.

Q Now, Doctor, the way you advocate the use of IVC filters, is that different from maybe some of the other specialties or even some of your colleagues choose to use IVC filters?

A I think in the hematology community, my opinions are similar to many other hematologists. And that may be because

we have a lot of familiarity with anticoagulants and know who we can use them in and who we can't use them in safely and have a very high comfort level of using drugs to treat blood clots. It may be different in the vascular surgery community or in the interventional radiology community.

Q Now, are you here to criticize or do you have criticism of the manner in which the IVC filter was used in Mrs. Hyde's case? In other words, the decision to use an IVC filter?

A Not at all because I -- yeah, I didn't -- yeah, I didn't look at those records and don't have any opinion on that.

Q Doctor, the opinions that you rendered today, are they to a reasonable degree of medical certainty?

A Of course, sir. Yes.

MR. LOPEZ: That's all the questions I have at this time.

THE COURT: Cross-examination?

MR. CONDO: Yes, Your Honor.

Thank you, Judge.

C R O S S - E X A M I N A T I O N

BY MR. CONDO:

Q Good afternoon, Doctor.

A Good to meet you.

Q Let me see if we can start with a couple points of agreement between you and I.

As a hematologist, you don't place IVC filters;

14:14:54 correct?
A No. I -- generally my role in that would be that I am asked to see somebody who is having difficulty with a blood clot, is post-op or bleeding heavily, and then I advise the
14:15:08 medical physicians or the surgical physicians caring for that patient that they ought to contact either a vascular surgeon or, more often, an interventional radiologist about such a device. They would be asking my opinion on that.
Q But you yourself do not place and have never placed an IVC
14:15:22 filter in a patient; correct?
A That's absolutely correct, yes.
Q And you've never removed or retrieved an IVC filter from patient; correct?
A No. No.
14:15:31 Q Correct statement?
A Yes, that's correct.
Q Okay. And I believe you told the jury just moments ago that in your personal practice you use anticoagulation as the primary treatment --
14:15:46 A Yes, sir.
Q -- for blood clots or DVT. And if you use anticoagulation, you don't feel that there's any reason to use an IVC filter; correct?
A Correct.
14:16:00 Q But conversely, if for some reason a patient can't accept

anticoagulation therapy or it has failed in the patient, then you do recommend, from time to time, the placement of IVC filters, don't you?

A I would say -- so I'd qualify that in -- if I have a patient who has an acute deep vein thrombosis in the first few weeks after having their events and they cannot be placed on the anticoagulants because they're already bleeding or they're at very high risk for bleeding, they've just had a major surgical procedure where bleeding is in an area where it could cause major harm, then that would be a patient that I would, you know, tell the people I'm consulting for that they should consider an IVC filter.

As far as failure of anticoagulation, I don't think I've ever placed one for that because most of the time, if there's a failure of anticoagulation, either the wrong drug's being given, the wrong dose is being given, there's some other issue you can fix medically, generally. You don't have to use a filter.

Q So in the subset of patients where you would recommend the placement of an IVC filter, you believe that that would be an appropriate and proper method of treatment for the patient; correct?

A Yes. I think when you're in that patient population where you have -- you can't use blood thinners and they're at risk for a pulmonary embolism, you have to do something, and

although we don't have very high quality data to support that intuit, you know, you have to do something. And so in that case, that's the patient population that I would place a filter in.

Q And I think you would agree with me that in that subset of patients, you previously described IVC filters as representing an important alternative to therapy.

A Certainly. And still do think of them in that when you can't do anything else and you have to prevent the pulmonary embolism from --

Q And I think you also described IVC filter implantation in that subset of patients as being an important weapon in every clinician's toolbox, so to speak, when treating patients?

A True. I think it is in that small segment of the patient population, I think you have to -- you can't do nothing. It's not acceptable.

Q Right. You can't do nothing.

A Right.

Q And when you can't do nothing, do you something; correct?

A Yes.

Q And when you recommend the implantation of an IVC filter, it's because, as you testified earlier, you thought or you assumed that the filter will catch clots before they reach the heart and lung; correct?

A True. That's -- that's -- the supposition is that they

form a barrier to a clot going to the heart.

Q And you've testified that pulmonary embolisms are serious medical events; correct?

A Yes.

Q And they are potentially fatal; correct?

A Yes.

Q And when you recommend the placement of an IVC filter in a subset of patients where you believe it is appropriate, you are doing that because you believe that you are potentially installing a lifesaving device in that patient; correct?

A I think there's -- well, as I said before, we don't have good data that they save lives because the studies haven't been done. But I would say that based on the data we have, let's say there's a very old study that looked at not treating patients with pulmonary embolism at all back in the 1960s randomized trial, no anticoagulation versus anticoagulation. People in the no anticoagulation arm, 25 percent of them died of a pulmonary embolism and 50 percent of them had a recurrent event. So this is back in the '60s, before we thought anticoagulation was safe.

So based on that experience and the clot rates with a pulmonary -- with a vena cava filter in the 3 to 5, 6 percent range, they probably -- you know, it's extrapolation, but they probably cut down on pulmonary emboli happening. But we don't have high-level data. You're kind of taking data from here

14:20:05 and data from here and making a decision.
Q Actually, I'm not. I asked a simpler question.
A Sorry. I tend to go on.
Q If -- you have to do something, as you testified, and that
14:20:16 something is implanting an IVC filter; correct?
A And that's my rationale for it, is that -- that analysis I gave you.
Q And that is because the doing something will potentially save the life of the patient from a pulmonary embolism that
14:20:34 could be fatal; correct?
A "Potentially" is important in that phrase. Potentially. We don't have -- that evidence level is not high, but potentially. Yes.
Q So you agree with my statement that you are implanting or
14:20:49 recommending the implantation of an IVC filter in that subset of patients because potentially it will save the plaintiff's life -- the patient's life in an event of a pulmonary embolism; correct?
A Yes.
14:21:06 Q Thank you.
Now, you're aware that statistics show that several hundred thousand people each year suffer from pulmonary embolisms?
A Yes, sir. There are various estimates out there, but that
14:21:17 sounds accurate.

14:21:18 Q And you're also aware that of those people afflicted with pulmonary embolism, numbers in the hundreds of thousands between, 100- and 200,000, die each year as a result of pulmonary embolisms; correct?

14:21:34 A I would say in U.S. that sounds high. I mean, the estimates vary about anywhere from 30- to 50-, sometimes as high as 100,000. Many of those -- unfortunately many of those patients don't ever come -- they're having sudden death events outside of the hospital, so most have not seen medical -- a

14:21:51 medical facility when they die, unfortunately.

Q But --

A So a lot of those events, deaths are in the first 30 minutes or so. Yes.

Q But I think you've written at least once that pulmonary

14:22:00 embolism is the most deadly form of venous thromboembolic disease; correct?

A Yes. Correct. Yes, sir.

Q Now, you were asked a series of questions about randomized studies. I want to talk about that and those studies. But

14:22:30 before I do, I want the jury to have a little bit more background on your experience.

You would agree that Johns Hopkins is probably one of the leading medical centers in the world?

A Yes. It's a very good institution.

14:22:46 Q And at Johns Hopkins, even today, you are aware that

14:22:52 interventional radiologists and others place IVC filters in patients.

A Certainly.

Q And you're aware of doctors at Johns Hopkins who implant
14:23:04 IVC filters even when anticoagulants are being administered to the patient; correct?

A It's possible. I wouldn't --

Q You wouldn't do it.

A I wouldn't do it, but there are certainly -- I mean, there
14:23:16 certainly may be people that are doing that, yes.

Q And you're also aware there are doctors at Johns Hopkins who place IVC filters prophylactically where the patient doesn't have a history of DVT or pulmonary embolism, but the patient is at risk and coagulants are contraindicated.

14:23:38 A I'd say that is a decreasing number of patients, but yes. More popular in the past, less common now. But let's say there's still probably some being placed like that.

Q And I think you told us that as a hematologist, you probably approach the practice of management of blood clots
14:23:59 and pulmonary embolisms a little more conservatively than perhaps interventional radiologists?

A Or differently, certainly. Just we see a different patient population and so --

Q Well, you would agree --

14:24:15 A -- our experience is different.

14:24:16 Q I acknowledge the experiences are different. But you would agree with me that generally in your practice, you have a more narrow view of when filters are appropriate than interventional radiologists.

14:24:27 A Yes. I think that's been -- in the past, it's been even -- there are even bigger differences. I think the number of indications that people think is appropriate has decreased over time because of evolving medical literature.

Q And you would agree with me some of the major physician

14:24:48 organizations have differing criteria than you do for when it is appropriate to implant filters; correct?

A Yes, sir.

Q You agreed quickly, so --

A I --

14:24:56 Q The Society of Interventional Radiologists have broader criteria than you do for when implanting a filter is appropriate?

A I'm certain they do, yes.

Q Okay. And you also know that the FDA has cleared filters

14:25:10 for indications that are broader than what you would recommend; correct?

A True. Sure.

Q So we can agree that various types of physicians have disagreements or at least differing criteria as to when IVC

14:25:25 filters should be implanted; correct?

14:25:28 A True.
Q Some patients are at risk for developing DVT and pulmonary embolism are at greater risk for developing DVT and pulmonary embolism than others; correct?
14:25:46 A Yes, sir.
Q And you would agree that anticoagulants themselves are not without risk.
A No. Of course not. Yeah.
Q There are sometimes fatal bleeding events that can be
14:26:02 associated with the taking of anticoagulants; correct?
A Certainly. Yeah. Small percentage. I'd say, you know, it's getting -- with newer drugs it's gotten better and our control of warfarin has gotten better. So I would say that if you look at recent studies with rivaroxaban, Xarelto,
14:26:18 apixaban, it is a fraction of 1 percent, maybe .5 percent fatal bleeding events in a year of patients on that drug.
Q Historically, going back even 20 years, those rates have been as high as 7, 8 percent, and have been coming down, haven't they?
14:26:36 A I would say it depends on what patient population you focus on and management of the anticoagulation, if it's good or not so good. So with warfarin in people that are -- where it wasn't managed well and you have patients that are -- as you get older, you are at higher risk for bleeding, that you
14:26:53 could get into those ranges, although I think that would be

rare now with conventional management.

Q Over the course of the last 20 years, there are patient populations that have experienced 7 to 8 percent fatal bleeding events associated with the taking of anticoagulants; correct?

A Seems -- 7 percent seems high. Major bleeding, yeah, I'd say 7 to 8 percent is reasonable.

Q 5 percent?

A I'd still -- fatal -- it still seems high to me, unless you had an extraordinarily high-risk population. So I'd have to -- it's -- have to look at the study.

Q I'm sorry.

Even patients who are on anticoagulation, a small number of them may suffer from a pulmonary embolism anyway; correct?

A Yes. Small number, yes.

Q So if you just anticoagulate a patient, there is a risk of fatal bleeding; correct?

A Yes. Small, but it's a risk. It's not zero.

Q And there is a risk that even with anticoagulation, the patient may suffer a pulmonary embolism; correct?

A Yes. It's small again, but not zero.

Q And are you aware of reports of patients who have died from a pulmonary embolism while taking anticoagulants?

A Yes. Again, it's a small number, but not zero. I would

say, again, in those -- if you look at the recent large randomized studies where -- you know, these new drugs, rivaroxaban, it is a fraction of 1 percent of people. I think there's a 2 out of 2400 patients in the Xarelto arm who had a fatal pulmonary embolism, so it's small, .1 percent or so, but it's not zero.

Q Let's talk about the two PREPIC studies. The two studies that were done in France.

A Um-hmm.

Q On direct you told the ladies and gentlemen of the jury that both studies were done in France?

A Yeah. Largely. Both the principal investigators for both studies were from France, but they had -- it's a multicenter study so there may have been some other European centers involved.

Q It wasn't done in the U.S.?

A I don't think so. I don't think there are any centers in the U.S.

Q And the PREPIC 1 study only used permanent filters; correct?

A True. It used vena type filters, Greenfield filters, Bird Nests. You know, all permanent filters. Many of them not used much anymore.

Q And that study concluded after an eight-year follow-up in 2008; correct?

14:29:28 A Yes, sir.
Q And then there was a second PREPIC study that involved optional filters or retrievable filters; correct?
A That's true.
14:29:39 Q But none of those optional filters were filters that were -- are used here in the United States; correct?
A I think the ALN filter has some utilization in the U.S. That's the one filter they used in that study.
Q They only used one filter manufactured outside of the
14:29:54 U.S., the ALN filter; correct?
A Yes.
Q They didn't use the Greenfield filter?
A No, because that is a permanent filter. But yeah, you're right. They didn't use -- I think they got support from the
14:30:05 manufacturers of ALN for that study. I think they got the devices. So it was just that device.
Q None of the filters that we're talking about here -- the G2, G2X, or Eclipse -- were part of either PREPIC study; correct?
14:30:20 A That's true.
Q And these weren't actually blind randomized studies because the patients knew what they were getting; correct?
A That's true. These were open -- both were open label studies, although the end points were adjudicated by people
14:30:36 who didn't know who got a filter and who didn't get a filter,

but the physicians placing the filters and the patients knew they had a filter or didn't have a filter.

Q And you've actually criticized both studies because the physicians knew who got which filters?

A Yeah.

Q You thought that affected the results; correct?

A Well, it could. I mean, it's a limitation because if you know someone has a filter or doesn't have a filter, your suspicion if they have shortness of breath for moving to the next step, getting a pump or a CT scan may be different if you have -- know they have a filter or don't have a filter. So that's why blinded studies are better, because you don't -- you don't -- your judgment's not clouded by knowing what their treatment was.

Q Has any IVC filter manufacturer that you're aware of done a randomized controlled blind clinical study to determine the efficacy or effectiveness of IVC filters?

A Not that I know of, no.

Q None in the United States?

A None in the United States.

Q None outside of the United States that you're --

A No. There's no blinded randomized trials in this area of medicine.

Q So Bard's not unique in not doing one of these studies; correct?

14:31:48 A True. I mean -- although -- yeah.
Q Now, these filters -- these two studies, in both studies, the patients were anticoagulated; correct?
A That's true.
14:32:04 Q There were 400 patients in PREPIC 1, as I recall?
A Correct.
Q And 200 received anticoagulation?
A Yes, sir.
Q And the other 200 received anticoagulation plus the
14:32:17 filter?
A Yes, sir.
Q Okay. There has never been a study that you're aware of that measured the efficacy of filters, just one population of patients with filters versus one population of patients
14:32:37 receiving just anticoagulants; correct?
A Oh, yeah. So where the filter arm didn't get any anticoagulation, true, that's never been done.
Q Okay.
A To my knowledge. Yeah.
14:32:48 Q And probably ethically couldn't be done; correct?
A Yeah. I think it would be tough to do that study.
Q Now, we talked about internal risk assessments as the kind of information that you thought manufacturers should supply to physicians like yourself, clinicians like yourself with
14:33:15 respect to how their products perform. Agree?

14:33:23 A True. So if they see from reports, their own internal reports coming back from the field that there's a certain increase in a certain adverse event with their device or their drug, they should make the physicians that use that device or
14:33:41 drug aware of it. If it looks like there's a problem that needs to be fixed, then I think they would to not only make them aware of it, but also, depending on the disparity between different devices, consider removing that device or drug from the market to repair that.

14:34:01 Q From the other IVC retrievable filter manufacturers that you're aware of, have you seen internal risk assessments of what you're talking about?

A No. No.

Q So Bard is not --

14:34:14 THE COURT: Hold on we're going to take a break here, Mr. Condo.

MR. CONDO: Thank you.

THE COURT: We will resume, ladies and gentlemen, at 10 minutes to the hour. Please remember not to discuss the
14:34:21 case. And we will see you then.

(Recess taken from 2:34 to 2:49. Proceedings resumed in open court with the jury present.)

THE COURT: Thank you. Please be seated.

You may continue, Mr. Condo.

14:50:08 MR. CONDO: Thank you, Your Honor.

BY MR. CONDO:

Q Doctor, where we left off, I had asked you whether or not in your experience you had received internal risk assessments from other IVC filter manufacturers, and your answer to me, as I recall, is you had not experienced that; correct?

A No, no, haven't seen any internal risk assessments from other companies.

Q And my follow-up question, then, is Bard, then, is not unique among IVC filters in not providing you with internal risk assessments; correct?

A True. I would say it would be good, though, if there's a problem, that that would be transparently transmitted.

Q But they're not the only IVC filter manufacturer who doesn't give you --

A Right.

Q -- internal risk assessment.

A Yes.

Q Now, turning back to the PREPIC tests, one of the sets of data that was collected in the PREPIC studies were incidents of symptomatic PE experienced by participants in the study, patients; correct?

A Yes, sir.

Q Now, to be clear, the PREPIC study -- PREPIC studies were not head-to-head studies comparing the benefits of IVC filters versus coagulation therapy; correct?

14:51:37 A No. It was kind of added on top of it as an extra treatment.

Q So my statement is correct?

A True. Yes.

14:51:46 Q And patients were excluded from the PREPIC studies if they had a contraindication to anticoagulant therapy; correct?

A Yes, sir.

Q So one of the criticisms of the PREPIC studies is that they did not include the very patients for whom you believe

14:52:13 IVC filters are most appropriate; correct?

A Yes, I think that's -- it would be good to do a study that at least approached a population where you're testing the filter's -- I guess where you're testing against less than full-dose anticoagulation. And, unfortunately, that hasn't

14:52:39 happened.

Q And a further criticism of the PREPIC studies is that the patients were not the typical patients who received IVC filters; correct?

A I guess they're not, at least for my population of

14:52:59 patients. Right. They're people that couldn't get anticoagulation. I think they were one of indications where both studies included people that were at a very high risk for having another pulmonary embolism. There are people that had unprovoked blood clots, had pulmonary emboli already and were

14:53:17 considered at high risk for having another pulmonary embolism.

14:53:20 So they were a high-risk population where some, certainly one of the indications in the past that some have promoted filters for was prevention of a possibly fatal event in someone that's on anticoagulation, so adding it on top of anticoagulation 14:53:41 would give added benefit.

Q But they weren't the typical patient population of the kind of patients for whom you recommend IVC filters because all of the participants in the PREPIC study were administered anticoagulants; correct?

14:53:57 A True. Although I think, to further expound upon that, that the -- particularly the second study where they were placing retrievable filters in people at high risk for having another event, one of the indications you might have seen in the SIR document for a filter, patients that are at high risk 14:54:15 for having another event, and so you're adding a filter on top of that, that study basically has dissuaded us now for -- or provided evidence we don't need to do that even if they're high risk for having a pulmonary embolism because adding a filter didn't add anything in that second study. There was no 14:54:35 difference. In fact, there were a few more pulmonary emboli numerically in the filter group than there were in the non-filter group.

Q Let's look at some of the results of the PREPIC 1 study with respect to symptomatic pulmonary embolism.

14:54:57 A Sure.

14:54:58 Q You would agree with me in PREPIC 1, the results there showed in the first eight to 12 days after implantation, filters were associated with a significant reduction in pulmonary embolism?

14:55:13 A That's true. At eight to 12 days in this study, unlike the second study, they screened everybody for having pulmonary emboli so they redid another scan, they did a ventilation profusion scan, to look for clots. So they picked up some asymptomatic clots and then there were some people that had

14:55:34 symptomatic clots. And if you add both asymptomatic and symptomatic pulmonary emboli at the eight- to 12-day window, there were fewer in the filter group.

Q Correct. So it was a correct statement that in PREPIC 1 in the first eight to 12 days, filters were associated with a

14:55:50 significant reduction in pulmonary embolisms; correct?

A Yes, at eight to 12 days.

Q And at the 12-day mark there were zero pulmonary embolism deaths for the filter-plus-anticoagulation group compared to four --

14:56:07 A True.

Q -- pulmonary embolism deaths related to the anticoagulant-only group; correct?

A True.

Q At --

14:56:17 A Sorry.

14:56:18 Q At the 12-day mark, besides showing fewer pulmonary embolism deaths associated with the filter group, fewer people also suffered a PE; correct?

A True. For total pulmonary embolism, yes.

14:56:34 Q Two for the filter group experienced a pulmonary embolism versus nine patients who only had the anticoagulant administered experienced pulmonary embolism; correct?

A True. With -- but with these permanent filters that were --

14:56:53 Q And after two years, symptomatic pulmonary embolisms occurred in six patients with one death in the filter group but 12 deaths, 12 patients with five deaths in the non-filter group; correct?

A True. Yes.

14:57:13 Q In other words, there were six more symptomatic pulmonary embolisms and four more deaths after two years in the non-filter group in the PREPIC 1 study; correct?

A True.

Q Now, there was an eight-year follow-up study in the

14:57:33 PREPIC 1; correct?

A Yes. Although I guess two years wasn't statistically significant, but it was numerically more.

Q At the eight-year mark in this follow-up of PREPIC 1, the filter-plus-anticoagulant group had nine symptomatic PEs

14:57:52 versus 24 symptomatic PEs experienced in the non-filter group;

14:57:58 correct?
A That's true. I would point out that in this study, why you see dramatic differences between this study and then when you look at the second study and I think the differences you
14:58:11 see there are differences in anticoagulation. In the older study, after three months, many, many people stopped anticoagulation. So there was only about 60 percent of people on anticoagulation beyond three months, and at eight years there were only 30 percent, 38 percent or so, that stayed on
14:58:27 the whole time. So a lot of the people -- nowadays we extend anticoagulation much longer. So I think that's why you don't see it in the second study when they looked earlier where I think anticoagulation -- I think -- anticoagulation has advanced since the 1990s.
14:58:43 Q Well, let's keep talking about PREPIC 1 and then we'll talk about PREPIC 2.
A Okay.
Q At the eight-year follow-up mark of PREPIC 1, there were two deaths in the filter group compared to 24 in the
14:58:58 non-filter group; correct?
A For pulmonary embolism?
Q Pulmonary embolism.
A Okay. Yeah, I think that's correct. I'd have to look --
Q At the eight-year mark there were two deaths from
14:59:11 pulmonary embolism and those patients who had an IVC filter

14:59:17 implanted, compared to 24 deaths from pulmonary embolism in those participants who didn't have an IVC filter implanted; correct?

A Yes, I think that's correct. I'd have to look at the

14:59:32 study to see if that's actually correct.

Q So we can agree that at least at the eight-year follow-up mark there's at least some evidence that having a filter in place reduced the risk of symptomatic pulmonary embolism for those patients; correct?

14:59:45 A Yeah. I would say, again, it would be in patients that those are people that probably would have been on anticoagulation nowadays that are not, and there were permanent devices, not Bard filters. So we don't know.

Q And you would agree with the conclusion of the authors of

15:00:03 the PREPIC 1 eight-year follow-up study that vena cava filters in patients with deep vein thrombosis, with or without pulmonary embolism, protect against the long-term development of pulmonary embolism without favoring the development of post-thrombotic syndrome?

15:00:26 A So I'd say I'd qualify it. Yes, in people if you stop anticoagulation in general after three months, that they probably help you prevent some pulmonary emboli in that case. Although that would be considered antiquated therapy now. As far as post-thrombotic syndrome, not a good study to look at

15:00:48 post-thrombotic syndrome because over 30 percent of the

15:00:51 patients already had clots before, so they already likely had post-thrombotic syndrome already started before they started the study.

So to really look at post-thrombotic syndrome in a 15:00:59 clean fashion, you have to have people that have never had clots before, because once you have a DVT, you start -- a lot of people, up to 50 percent of the people, develop post-thrombotic syndrome. So it wasn't a good study to look at post-thrombotic syndrome.

15:01:14 Q And you agree with the authors of the PREPIC 1 study group follow-up when they wrote, "The filter insertion remains significantly associated with reduction of pulmonary embolism"?

A I think yes, in people that did not -- not -- if you don't 15:01:29 put on anticoagulation for an appropriate period of time, that it does something. Which is why I think we should use it in that population where you can't use anticoagulation.

Of course also in that group there were 14 percent of people had IVC thrombosis that had filters too. So that's a 15:01:48 downside of filters. And there were more DVTs too. So --

Q Let's talk about PREPIC 2, then. That was published in 2015?

A Yes, sir.

Q And it, too, is not a head-to-head study comparing IVC 15:02:01 filters to anticoagulants?

15:02:03 A Right. Yeah.
Q And many of the same limitations that you and I discussed, the criticisms that you have of PREPIC 1 apply to PREPIC 2; correct?
15:02:11 A True. An open, study. Yes.
Q An open study. And everyone received anticoagulation, even those with filters.
A Yes. So the only question you were testing then was can filters in people that are at very high risk for having a
15:02:24 pulmonary embolism, do they add anything to anticoagulation. And I think this study definitively showed that they don't.
Q Now, the study did not involve any Bard filter; correct?
A True. None of these studies involved Bard filters.
Q This was the ALN filter?
15:02:42 A Right. A French retrievable filter; correct.
Q You'll agree with me PREPIC 2 showed that after the eight-year mark, those in the filter-plus-anticoagulant group had ten fewer symptomatic PEs?
A I don't think they have ten-year follow-up or eight-year
15:02:58 follow-up.
Q I'm sorry.
A I think there's confusion.
Q Two-year mark.
A Two-year mark. I think they have three-month and
15:03:06 six-month follow-up on PREPIC 2. Or are we on PREPIC 1? I'm

15:03:10 confused.
Q I meant to go to 2 and I looked at a question from 1. My apologies.
A Oh. Okay. Sure.
15:03:18 Q Between having a recurrent DVT and a pulmonary embolism, is having a pulmonary embolism a greater risk to one's life?
A I think, yeah, one to one if you have -- you'd rather have a DVT than a pulmonary embolism.
Q And like PREPIC 1, patients in PREPIC 2 were
15:03:37 contraindicated and could not receive anticoagulation; correct?
A True. Yes, you had to be a candidate for anticoagulation for both those studies.
Q Neither of the PREPIC studies, including PREPIC 2,
15:03:49 addresses the benefits of IVC filters in patient populations where anticoagulation is not an option; correct?
A True. That's where -- I think that's one of the holes in the literature. Although Anita Rajasekhar's study would have been doing it in people that are at high risk but on -- high
15:04:13 risk on prophylactic dose anticoagulation might have been a better approach to try to get at that where you don't have full-dose anticoagulation, and get closer to a test of what filters bring.
Q In neither PREPIC 1 nor PREPIC 2, the results can be used
15:04:29 to say that filters, just filters, versus just anticoagulants

is better one than the other; correct?

A Right.

MR. CONDO: I have no further questions. Thank you, Your Honor.

THE COURT: Redirect?

MR. LOPEZ: Thank you, Your Honor.

R E D I R E C T E X A M I N A T I O N

BY MR. LOPEZ:

Q So let's -- I got kind of lost in all those numbers for PREPIC 2, Doctor.

MR. LOPEZ: Can you put up so Dr. Streiff can see it Exhibit 3709.

BY MR. LOPEZ:

Q If you need to read it -- actually --

A Yeah.

Q -- I'd ask you to read the "Conclusions" section. In other words, you just got cross-examined on all of the data that was in that study and I want the jury to know what the bottom line conclusions were from PREPIC 2 that you just went through. Could you just read that word for word, please.

A Yeah. So authors at the end conclude "vena cava filters reduce the risk of pulmonary embolism but increase the risk of deep vein thrombosis and had no effect on survival."

Q That was actually PREPIC 1; right?

A Yes. Eight-year follow-up, yeah. That's 3709, yeah.

15:06:06 And then PREPIC 2 --

Q Hold on. Before you go on.

One of the conclusions there was while it reduces the risk of pulmonary embolism, which caused no harm, it had no 15:06:20 effect on fatal pulmonary embolism, the reason that you would prescribe an IVC filter, is that correct, Doctor?

A It wasn't a significant reduction, I guess, in that. I'd have to go look at the tables to see if --

Q Now let's look at PREPIC 2. 4147.

15:06:37 Let's go to that first page and the "Conclusions." In fact, it says "Conclusions and Relevance," does it not, at the bottom?

A Yes, sir.

Q What does that mean when authors put that in an article 15:06:54 like this?

A So the relevance to your current medical practice. Whether you -- what -- how do you translate these results into what you're going to do with patients.

Q Is it a takeaway message, basically, from the study and 15:07:05 the data that's in the study that the authors want the readers to have?

MR. CONDO: Objection. Leading.

THE COURT: Sustained.

THE WITNESS: I would say --

15:07:13 THE COURT: Hold on, please. Let's wait for a new

15:07:15 question.

THE WITNESS: Oh.

BY MR. LOPEZ:

Q So let's read that, Doctor, the "Conclusions and

15:07:19 Relevance."

A So --

Q "Among hospitalized patients" --

A Yeah. "Among hospitalized patients with severe" --

MR. LOPEZ: Can you make that bigger?

15:07:29 THE WITNESS: -- "acute pulmonary embolism, the use of a inferior vena cava filter plus anticoagulation" --

THE COURT REPORTER: Excuse me, Doctor. I need you to read slower.

BY MR. LOPEZ:

15:07:38 Q Slow down.

A I'm sorry. Should I start again?

Q Please. And just read very slow.

A "Among hospitalized patients with severe acute pulmonary embolism, the use of a retrievable inferior vena cava filter

15:08:02 plus anticoagulation compared with anticoagulation alone did not reduce the risk of symptomatic recurrent pulmonary embolism at three months. These findings do not support the use of this type of filter in patients who can be treated with anticoagulation."

15:08:29 Q I also don't want this to be lost, Doctor. In the

15:08:33 "Results" part, the three of the patients that died with a filter, they not only had a filter in them, they had the added protection of anticoagulation. True?

MR. CONDO: Leading.

15:08:50 THE COURT: Sustained.

THE WITNESS: True. We went over this --

THE COURT: Sir, when I sustain an objection you need to wait for another question.

Go ahead, Mr. Lopez.

15:08:56 BY MR. LOPEZ:

Q Doctor, in the group that had a filter, did anticoagulation give them added protection against a clot?

A No, it did not. This study showed that there's no utility in adding a filter to patients you can give anticoagulation, even if they're at high risk for pulmonary embolism.

15:09:13 Q So did the group which had the higher fatalities actually have two modes of treatment that were meant to protect them from a fatal pulmonary embolism?

A True. So filters didn't add anything. And numerically there were more fatal pulmonary emboli -- in this study, more numerically pulmonary emboli in the filter group than there were in the non-filter group. Kind of the reverse.

Q Mr. Condo asked you, has any IVC filter manufacturer ever done a study like the one you're suggesting. Remember that?

15:09:54 A True, and I think --

15:09:55 Q Hold on. You think it's an excuse for a company not to do the kind of safety and long-term efficacy study necessary to answer some of the questions we've been talking about today just because their competitors are not doing it?

15:10:11 A No, and I think that's an opportunity for them to prove the value of their product.

Q And, by the way, how do these two studies he just criticized, the one in 2005 and 2013 that did not include Bard filters, compare to similar studies Bard sponsored and

15:10:29 conducted?

MR. CONDO: Objection, Your Honor. This goes beyond the scope of the cross.

THE COURT: Sustained.

BY MR. LOPEZ:

15:10:39 Q Now, he also talked about the type of patient population that you treat -- that you decided to treat with these filters. This is generally a very sick patient population?

A True. These are very sick patients where you want to use the best available device. You want to use the device with

15:10:55 the least chance for failure, for side effects. That's why it's very important to know device characteristics when you're giving advice to physicians that are treating someone who's very sick and you can't treat them with anticoagulation. You want the safest device, most effective device.

15:11:12 Q My question is going to be just because this is a sick

patient population, would their desire to have the safest device be different than a population that wasn't that sick?

A No. Actually would be more, I would think. You have less chance for -- the -- I guess margin of error is much smaller.

Q Let me ask you this: Do they have less rights to know about safety information that you expect to get from a product manufacturer just because they're a sicker population?

A No. No.

Q And he asked you some questions about the FDA's cleared indications. Does the FDA treat patients?

A No, they --

Q Do they design medical devices like IVC filters?

A No.

Q Do they test them?

A No. They rely on the test results that are submitted to them to make a determination if it should be on the market.

Q Now, you heard the name of a filter called an ALN filter. Are you familiar with that filter?

A Yes, sir.

Q And that filter is -- that was used in the PREPIC study. Do you know whether or not, because they used an ALN filter, whether or not you have information that the patients were put actually at a lesser risk of complications because they used an ALN filter versus a Bard filter?

A Well, I mean, you -- obviously in that study there weren't

any Bard filters. But if you look at the studies that have been done with Bard filters and ALN filters, ALN filters, at least if you do a head-to-head comparison, obviously it's not a randomized study between an ALN filter and a Bard filter, but if you look -- because none of the companies have compared their filters head-to-head, but if you look at the outcomes for ALN filters versus outcomes for Bard filters or OptEase filters, Bard filters have higher rates of fracture and higher rates of migration and higher rates of IVC penetration than ALN filters or OptEase filters.

Q Let me ask you, Doctor, do you know if ALN filters have the history of fractures like the history that Bard has experienced with their G2 family of filters, including the Eclipse, where the fracture doesn't stay where it is but it actually embolizes to people's hearts and lungs and sometimes die?

MR. CONDO: Objection --

BY MR. LOPEZ:

Q Do they have that in their history?

THE COURT: Hold on.

What is the objection?

MR. CONDO: The scope of the cross and it's a nondisclosure issue.

THE COURT: I'm going to sustain on the second ground, not the first. I think it was within the scope.

Well, I should ask you, is that disclosed, Mr. Lopez?

MR. LOPEZ: No, but he -- he crossed him on the use of ALN filters versus Bard filters.

THE COURT: I think your last question was fair game on that. I think this does call for an affirmative opinion.

BY MR. LOPEZ:

Q Do you know if Bard has ever sponsored a registry to follow patients on any of their filters to see how they're performing?

MR. CONDO: Your Honor, could we approach?

THE COURT: Yes.

If you want to stand up, ladies and gentlemen, feel free.

(Bench conference as follows:)

MR. CONDO: We crossed this bridge once before in the Booker trial when they wanted to raise the issue of this witness being approached by Bard to talk about sponsoring a registry. Much different than a clinical trial. And Your Honor prohibited them from getting into that area. It wasn't part of the expert opinion. It was a piece of fact evidence that it has to do with whether or not Bard does a study, not whether or not -- not his opinions about what Bard -- what physicians expect to be told or his survey of the medical literature, which is the two things he was disclosed on.

15:15:47 MR. LOPEZ: I think once you ask the question, have any -- has any manufacturer showed us their internal documents or shown internal documents, has any other manufacturer sponsored such a study, even if it's not in his report, the 15:16:01 fact he asked those questions, I have a right to come back on redirect and rehabilitate him on what he's putting in front of the jury. And the fact that none have done it, I think it's fair game that Bard had opportunities to do this, and he's aware of that.

15:16:21 THE COURT: To do what?

MR. LOPEZ: To do surveys and their own studies. In other words --

THE COURT: What is it you want to elicit?

MR. LOPEZ: There's two things. Number one is he 15:16:32 offered to do a study. He consulted with them. They came to him and got his advice as a hematologist ten years ago, maybe 12 years ago. His advice, had they called him back, would have been you need to do a long-term study to figure out whether or not these things work or whether or not they don't 15:16:50 work and what the risks really are with these devices.

The fact that he says --

THE COURT: Well, the question to you was what do you want to elicit.

MR. LOPEZ: The fact that he had that information and 15:17:05 he had those -- at least one meeting with Bard about that.

He --

THE COURT: Okay. That's what you want to elicit?

MR. LOPEZ: Yes.

THE COURT: I don't want to hear your argument about it, I just need to know what you want to elicit.

What is your objection to that, Mr. Condo?

MR. CONDO: Both relevance and nondisclosure. As we went through, this is exactly the argument Mr. O'Connor made in the Booker trial. They wanted to because we cross-examined on whether or not anybody had ever done a study. They wanted to come back and talk about the offer that -- the conversation he had between Bard and -- some unknown Bard person about doing this registry.

You asked a question: Did you list him as a fact witness on this issue?

And the answer was no.

Mr. O'Connor: I think he's just designated and disclosed consistent with the report and that was what he was deposed on and asked about. It wasn't part of his expert opinion. It was a fact piece of evidence you want to get in about Bard not doing a study. He's an expert witness. He needs to stick to his opinions.

This is exactly the same issue we crossed in Booker.

THE COURT: Hold on just a minute.

I didn't make a note last time.

15:19:24 What the witness has been asked on cross is whether any company has done this kind of a study, and he had said no, he's not aware of any.

It's been established on your direct that Bard has
15:19:41 never done such a study.

What I'm not understanding, Mr. Lopez, is -- you've established to the jury Bard's never done it. They've established to the jury nobody's ever done it. A direct contradiction of that would be, no, somebody has done it. But
15:20:15 that apparently isn't available.

What I'm wrestling with is why his conversation with Bard changes the fact that Bard never did it. Or no other company ever did it.

I mean, if the point you want to make to the jury is
15:20:33 Bard was approached and told to do it and never did it, that seems to me to be part of your affirmative proof if you want to criticize this company for not doing studies. And obviously you didn't list him as a fact witness on that point or put in a report.

15:20:48 I'm trying to figure out the line between fair cross and what gets into undisclosed affirmative evidence.

MR. LOPEZ: I know you are. I think because when they ask a question, they ask it for a reason. It's to leave the impression that none of these -- none of these companies
15:21:04 are doing studies. And therefore there's maybe not a reason

15:21:08 to do studies. That's a good enough excuse not to do a study. And I think now for me to be able to ask him -- this case should be about Bard and whether or not Bard had an opportunity, based on conversations he's had with them, to do
15:21:25 the kind of study that's not been done. You know. I mean, we've already established this study was done in 2005 and 2015.

THE COURT: But on that point, isn't -- you said to do the kind of study that's not been done. I think it's been
15:21:40 established in previous trials you can't do this kind of a study on the patient population for which filters are used. You can't tell people who are on anticoagulants, you get a filter, you don't, we'll see who dies.

So the fact -- you're not going to be able to have
15:21:59 this doctor say you can do those studies.

MR. LOPEZ: No. Actually there's -- I'm not going to, but there's actually an article that says you can actually do a study like that. There's a design for a study like that.

THE COURT: So what you want to do is say there's
15:22:14 something else they could have done that's a less-perfect form of a study that you talked to them about --

MR. LOPEZ: You know, I'm not going to pursue this. I think whatever you're going to leave me with won't be much anyway. I want to get him on and off.

15:22:29 THE COURT: Okay. And, by the way, on these kinds of

sidebars I'm splitting time. I'm not charging it all to one side.

MR. LOPEZ: Thank you.

MR. CONDO: Thank you, Your Honor.

(Bench conference concludes.)

THE COURT: Thanks for your patience, ladies and gentlemen.

MR. LOPEZ: Can you pull up Exhibit 3859, please.

BY MR. LOPEZ:

Q Dr. Streiff, you have Trial Exhibit 3859 in front of you?

A Yes, sir.

Q And is this an article written by a colleague of yours?

A Yes, sir.

Q Is it written in an authoritative journal by someone that you know to be an expert in the field?

A Yes, sir.

MR. CONDO: Objection, Your Honor. This beyond the scope of the cross.

THE COURT: I haven't heard any question yet so I can't determine that.

BY MR. LOPEZ:

Q And who is Anita -- I'm --

A Rajasekhar.

Q How do you pronounce that?

A Rajasekhar.

Q I'll let do you that.
A She taught me.
Q Who is she?
A She's a colleague. Hematologist at the University of Florida.
Q And she's someone who you've written this chapter with and that we talked about earlier?
A Yes. Yes. Has an interest in filters.
Q And could you please read the title of this article.
A "Pilot Study on the Randomization of Inferior Vena Cava Filter Placement for Venous Thromboembolism Prophylaxis in High-Risk Trauma Patients."
Q And this was published in --

MR. CONDO: Objection, Your Honor. This is a subject that was not addressed on cross.

MR. LOPEZ: It deals with --

THE COURT: Hold on just a minute.

Objection's overruled.

BY MR. LOPEZ:

Q Could you -- this was published in Trauma in August of 2011?
A Yes, sir.
Q And for the sake of time --

MR. LOPEZ: Felice, can you blow up the "Conclusion" section of that, please.

15:25:28 THE WITNESS: "Our pilot study demonstrates for the first time that a randomized controlled trial evaluating the efficacy of prophylactic IVC filters in trauma patients is feasible. This pilot data will be used to inform the design 15:25:49 of a multicenter randomized controlled trial to determine the incidence of PE and DVT in high-risk trauma patients receiving prophylactic inferior vena cava filters versus no prophylactic inferior vena cava filters."

BY MR. LOPEZ:

15:26:11 Q So according to your colleague, she successfully found a way --

MR. CONDO: Leading.

MR. LOPEZ: I'm sorry.

BY MR. LOPEZ:

15:26:21 Q What is the -- what is the conclusion -- what is the -- what is the message here from this study?

A So this purpose of this study was to show it's feasible in a test to randomize patients who are high risk for clots but don't have them yet that are not on full-dose anticoagulation 15:26:40 to show that they would decrease the incidence of pulmonary embolism in a patient population that's just getting low-dose preventative doses of blood thinners. And trauma patients are already at high risk for pulmonary embolism, and so this would be an ideal population to test this hypothesis. And, in fact, 15:26:59 trauma surgeons have often used filters without this data

because they were concerned about pulmonary embolism in their patients.

Q Are IVC filters -- have they been used in trauma patients extensively over the years?

A Yes, yes. As a prophylactic measure in people that could, or sometimes could not, receive prophylactic preventative doses of anticoagulation.

Q Do you know if any representative from Bard's approached you or your colleagues --

MR. CONDO: Objection, Your Honor.

BY MR. LOPEZ:

Q -- conduct such a study?

THE COURT: Sustained.

MR. LOPEZ: Those are all the questions I had.

THE COURT: Thank you, Doctor. You can step down.

MR. LOPEZ: Your Honor, plaintiffs are going to call Dr. Frederick Rogers by videotape at this time.

THE COURT: Is this from a deposition?

MR. LOPEZ: Yes, Your Honor.

THE COURT: Okay.

Ladies and gentlemen, let me give you an instruction on this.

A deposition is sworn testimony of a witness taken before trial. The witness is placed under oath to tell the truth and lawyers for each party may ask questions. The

15:28:42 questions and answers are recorded, in this case with a videotape.

When a person is unavailable to testify at trial, the deposition of that person may be used at trial.

15:28:53 The deposition of this witness was taken before trial. It's -- a portion of it is going to be played to you. Insofar as possible, you should consider deposition testimony presented to you here in court in lieu of live testimony in the same way as if the witness were to testify here in court.

15:29:15 And that instruction will apply to a number of different deposition excerpts you'll see during the trial.

All right. Counsel, I think, as in the previous trials, the understanding is the court reporter won't try to keep a record of what's on the tape, you all will submit that

15:29:31 in the deposition --

MR. LOPEZ: Yes, Your Honor.

THE COURT: -- transcript. Okay.

MR. LOPEZ: I'm going to read a stipulated background summary.

15:29:37 THE COURT: Let me give one other instruction, Mr. Lopez.

When you hear deposition excerpts played, ladies and gentlemen, to save time so you don't to have listen to any more than you need to, the parties have typically agreed on a

15:29:49 little summary that will describe who the witness is, what

15:29:51 their qualifications are, et cetera. These are agreed facts that will be read to you before these depositions, so you should take those as true. It's just to save time so that stuff doesn't need to be played to you.

15:30:02 Go ahead, Mr. Lopez.

MR. LOPEZ: Thank you, Your Honor.

Dr. Frederick Rogers specializes in critical care and has over 37 years of experience in the field of medicine. He is board-certified in surgery and surgical critical care. He

15:30:16 graduated from the University of Vermont College of Medicine with his medical degree in 1981.

In 2008 Dr. Rogers assumed the trauma medical directorship at Lancaster General Hospital, a Level 2 trauma center in southeastern Pennsylvania, and in January of 2017 he

15:30:37 became director of the Lancaster Hospital clinical research program.

He has conducted clinical research involving IVC filters for more than 20 years.

Dr. Rogers is not being presented as an expert

15:30:50 witness by either party.

(Video testimony of Frederick Rogers, M.D. was played.)

MR. LOPEZ: There was an answer there. I'm going to have to read it.

The answer was, "Yes."

15:41:34 THE COURT: Is that the end of the videotape?

MR. LOPEZ: Yes, it is, Your Honor.

THE COURT: Okay.

MR. O'CONNOR: Your Honor, our next witness is Dr. Robert McMeeking.

ROBERT McMEEKING,

called as a witness herein, after having been first duly sworn or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N

BY MR. O'CONNOR:

Q You can get yourself organized. Relax.

Would you introduce yourself to the members of the jury, please.

A My name is Robert McMeeking.

Q And, Dr. McMeeking, can you tell us what you do for a profession.

A I'm a professor of mechanical engineering and professor of material science and engineering and I teach and do research on those subjects at the University of California, Santa Barbara.

Q Tell us, what is a mechanical engineer?

A A mechanical engineer is someone who creates, designs, and analyzes mechanical devices and structures.

Q And does that include medical devices?

A It does. Medical devices are a special form of mechanical structures.

15:43:50 Q Can you explain to the members of the jury what your role here is in this trial.

A I've come here today to testify about the design and testing that Bard carried out on its inferior vena cava
15:44:06 filters. Particularly, the Recovery, the G2, the G2X, and the Eclipse filters.

I will tell you about the problems I found with those filters. For example, the problems with the resistance of the filter to fracture and its resistance to what's called
15:44:32 fatigue.

I will also tell you about problems I found that the filter is not safe for its intended use.

MS. HELM: Your Honor, may we approach?

THE COURT: Already?

15:44:46 MS. HELM: Yes, Your Honor.

THE COURT: Okay. Yes, you may.

(Bench conference as follows:)

MS. HELM: Your Honor, in your *Daubert* ruling the plaintiff stated that Dr. McMeeking was not going to offer an
15:45:18 opinion that Bard filters are dangerous. And I'm on Docket 10051 at page 8. And you said that defendants may object if they believe Mr. McMeeking -- Dr. McMeeking is rendering an opinion that Bard filters are dangerous.

I acknowledge he did not use the word "dangerous."
15:45:37 He used the word "not reasonably safe" or "unsafe."

15:45:41 The statute in Wisconsin --

THE COURT: Hold on just a minute.

Are you intending to elicit opinions from Dr. McMeeking that the Bard filter is not safe?

15:45:52 MR. O'CONNOR: Well, I think we're going to elicit opinions that it is not -- it's an unsafe design, yes.

THE COURT: Hold on. Let me read --

So you apparently said in your response to the *Daubert* motion, Mr. O'Connor, that Dr. McMeeking would give no

15:46:50 opinion that filters are dangerous or that they have dangerous complication rates or regarding their relative complication rates.

MR. O'CONNOR: He's not talking about complication rates. He's going to talk about how they fail and how those

15:47:13 failures are dangerous.

THE COURT: What's he going to say about how they're dangerous?

MR. O'CONNOR: Well --

THE COURT: It's one thing to say it fails for this

15:47:20 reason. It's another thing to say, and that makes the product dangerous to the patient.

MR. O'CONNOR: I don't know how we get around it because he's also going to testify, as you know, that there are safer alternative designs. "Safer" implies something that

15:47:34 is safer than a previous filter. And obviously the corollary

15:47:38 to that is that another device is not safe or dangerous.

THE COURT: Are you going to have him render an opinion that the Bard filters as designed are not safe?

MR. O'CONNOR: I believe so.

15:47:54 THE COURT: Based on what?

MR. O'CONNOR: Based upon his work and his opinions in this case.

THE COURT: Based on what? What is going to be the basis for him stating an opinion about whether or not they're

15:48:04 safe to patients?

MR. O'CONNOR: That filters are prone to all the complications -- that they tilt, they migrate, they penetrate, they fracture -- and that they are not safe for the use they're intended for when they're placed in the vena cava.

15:48:23 THE COURT: Okay.

Ms. Helm.

MS. HELM: Your Honor, I have a couple of statements to make. Number one --

THE COURT: You ought to listen to this because I'm

15:48:31 going to ask you to respond.

MS. HELM: Number one, there's no disclosure in any report or in any deposition in which he calls the filters unsafe. The only disclosure was his in his report which we addressed in the *Daubert* motion where he called them

15:48:49 dangerous. They said we're not going to call them dangerous.

15:48:52 And you said that we could object, that he cannot call them dangerous.

The Wisconsin statute uses the term "not reasonably safe" and "unreasonably dangerous" in two different sections 15:49:05 of the strict liability code. So they're one in the same.

He has not -- he has not disclosed that they're not safe for patients. He's never said that prior to today. So we have a nondisclosure. We did not have the opportunity to cross-examine him on that. And you've previously ruled that 15:49:27 he can't say they're dangerous.

THE COURT: So it's nondisclosure.

MS. HELM: It's both, actually.

THE COURT: Well, where is it in his report?

MR. O'CONNOR: We've got several reports. There's 15:49:36 several hundred pages.

THE COURT: Okay. Well, you need to show me where it is in his report --

MS. HELM: Your Honor, I will state --

THE COURT: Hold on.

15:49:43 MS. HELM: Excuse me.

THE COURT: That's the rule. If they challenge nondisclosure, you have to be able to show where it is.

MR. O'CONNOR: I'm going to have to move on. Right now I won't ask him about dangerous. I'll ask him what he did 15:49:51 to arrive at his opinions.

15:49:53 THE COURT: Okay. But before you elicit testimony it is unsafe or dangerous show me where it is in the report.

MR. O'CONNOR: He testified --

THE COURT REPORTER: Excuse me. Someone is rustling

15:50:02 papers and I can't hear.

THE COURT: Say that again, I think she missed it.

MR. O'CONNOR: I wasn't expecting this type of an objection this early because I think he has testified, and will continue to testify, along the same lines he's testified

15:50:21 in the other cases and in his depositions.

THE COURT: Okay. That's fair. If you could have somebody find it so that we can confirm the nondisclosure issue.

MR. O'CONNOR: All right. So I just want to make

15:50:31 sure I'm careful here. Here's the next thing I'm going to do. I'll stay away from that. I was going to have him give his opinions today, and he may give some. Just working backwards I'll try to do what I can to keep him from "dangerous." But he does have an opinion about the Simon Nitinol being a safer

15:50:52 design.

THE COURT: Is that disclosed?

MR. O'CONNOR: Yes.

MS. HELM: He was precluded --

THE COURT: I wasn't asking you that question.

15:51:03 MR. O'CONNOR: Oh. I'm sorry.

15:51:04 MS. HELM: Your Honor, I have to rustle papers again.
THE COURT: Just tell me if it's in there.
MS. HELM: In the *Daubert* ruling there's a specific line that says he cannot offer an opinion that the
15:51:11 Simon Nitinol is a safer alternative design for a particular plaintiff. And I can show you in your ruling.
THE COURT: Go ahead.
MR. O'CONNOR: I agree with that. I mean, he's not a medical --
15:51:21 THE COURT: Well, he's going to be on the stand for a while; right?
MR. O'CONNOR: Yes.
THE COURT: It seems to me you can go forward and cover a lot of ground without getting him to say anything on
15:51:31 safe or dangerous and we'll address this issue when we're not keeping the jury waiting and you can cover that ground in the morning, if I allow it.
MR. O'CONNOR: That's fine. But just so you know my intention, my intention is to follow your order and he's not
15:51:44 going to say anything about this particular patient other than this patient's filter experienced the failures he has studied and saw and tested.
MS. HELM: That's fair.
THE COURT: Okay.
15:51:55 MR. ROGERS: Your Honor, is today a 4:30 day?

THE COURT: Yes.

MS. HELM: Your Honor --

(Bench conference concludes.)

THE COURT: Thank you, ladies and gentlemen.

BY MR. O'CONNOR:

Q All right. Dr. McMeeking, I think we've got a lot of ground to cover, so I'm going to kind of go a different direction with you right now. And what I'd like you to do first of all is talk to the members of the jury and let's talk about your background, your qualifications to come here, and talk to them about filter -- Bard filters and their designs. Okay?

A Okay.

Q So let's start with if you could just talk us through and tell us what you did to become an engineer in the first place.

A Well, I went to University of Glasgow to do my undergraduate degree, where I earned a bachelor of science and engineering with first class honors, which is the highest grade of degree at Glasgow.

I then went to Brown University in Providence, Rhode Island, and I earned my master of science degree and my doctor of philosophy degree in engineering at Brown University.

Thereafter I went to the Stanford University and I began my teaching career as a professor, although I had been

15:53:29 teaching at Brown as a graduate assistant before I left there.

So I moved to Stanford and I was an acting assistant professor at Stanford for two years. Then I moved to the University of Illinois at Urbana-Champaign, where I taught for 15:53:43 seven years, and I was on the faculty of the Department of Theoretical and Applied Mechanics.

I then moved to the University of California, Santa Barbara, and I have been there since 1985. And as I mentioned before, I'm now a professor of mechanical 15:54:04 engineering and professor of materials science engineering there where I carry out research on those subjects and I teach those subjects as well.

And I teach a number of topics. I teach stress analysis, finite element computer analysis, stability of 15:54:21 structures, design of components and structures, behavior of materials, strength of materials, fracture of materials, fatigue of materials, and these are all issues which are involved in today's trial.

Q So did this all start at the University of Glasgow?

15:54:39 A That's correct.

Q Where are you from?

A I was born in Glasgow. So I'm a Glaswegian, which is somebody who's from Glasgow.

Q You became an engineer. And you're a Ph.D.; is that 15:54:53 right?

15:54:54 A That's correct.
Q What does that mean?
A A Ph.D. is a graduate degree in which the recipients of the degree are trained in doing research and creating
15:55:06 knowledge and passing that knowledge on to others in the field. And in my case it specifically was in the field of engineering.
Q So if we were at the University of California, Santa Barbara, and went to one of your classes, give us an
15:55:22 idea. Do you teach students at all levels in college?
A Yes, I do. I teach students from the sophomore level all the way to students who are well advanced in their graduate degrees. In fact, next week I'll start to teach a class to juniors on the computer analysis of and design of structures.
15:55:43 Q And do you teach subjects that are relevant to what you're going to be talking about here today?
A That's correct, yes.
Q What types of subjects?
A I teach the subjects that I mentioned earlier that range
15:55:56 from stress analysis, finite elements, stability of structures, behavior of materials, and the fracture and fatigue of materials.
Q Now, are you a member of professional organizations or honorary societies?
15:56:10 A Yes, I am. I'm an elected member of the National Academy

15:56:14 of Engineering. The National Academy of Engineering is a United States association which has about 3,500 members who are elected for the quality and impact, the high quality and impact of the engineering work that they've done. And I note 15:56:32 that there's 3,500 of us who are members and there's about one and a half million engineers in the United States who practice engineering. And so it's a very high honor to be elected to the National Academy of Engineering.

I'm also a fellow of the Royal Academy of Engineering 15:56:50 in the United Kingdom, which is the equivalent body in the United Kingdom. And I'm a fellow of the Royal Society of Edinburgh. The Royal Society of Edinburgh elects its members in a similar fashion. It's the national academy of Scotland.

I'm a life fellow of the American Society of 15:57:12 Mechanical Engineers, and life fellows are given that distinction and honor for the quality and impact of the mechanical engineering work they've done over their career.

Q And have you received honors and awards for your work in engineering?

15:57:24 A Yes. I was awarded the Timoshenko Medal of the American Society of Mechanical Engineers. The Timoshenko Medal is the highest honor and award that's given to those of us who practice stress analysis and solid mechanics, as it is known, and it's given to one mechanical engineer each year, and I was 15:57:49 fortunate enough to be awarded it in 2014.

15:57:58 Q Now, do you write authoritative articles?
A Yes. I write publications and papers on the research that I do and I publish them in the journals of my field, my fields, and these are articles which are peer reviewed.
15:58:17 They're inspected and assessed by other researchers, by other professors, by other Ph.D's to ensure that they're of the quality and significance and reliability that meets the standard of a peer-reviewed publication.
Q Have you written about any of the subjects that you're
15:58:39 going to address here in this court?
A Yes. I've written about 250 -- or over 250 peer-reviewed papers, and the topics that I've published on include stress analysis, finite computer analysis, strength of materials, behavior of hard and soft materials, fatigue of materials,
15:58:59 stability of structures, adhesion of biological cells and tissues to other materials and surfaces, the remodeling of biological cells and tissues, and also on medical implants, specifically prosthetic heart valves. So I've published papers in all of these areas and many are relevant to what
15:59:22 we'll be talking about today.
Q There are journals and periodicals that professionals in your field look to and review and rely for updated engineering principles?
A Yes. There are many journals that range from the solid
15:59:38 mechanics and stress analysis area, such as Journal of Applied

15:59:41 Mechanics all the way through to journals such as one called Biomechanics and Mechanobiology, which I also publish in, which are focused more on the biological end of the subjects I do research on.

15:59:59 Q Are you an editor for any professional journal in engineering?

A Well, I'm an associate editor or an editorial advisor for many journals. But from 2002 to 2012 I was editor-in-chief of the American Society of Mechanical Engineers Journal of

16:00:16 Applied Mechanics, which is the premiere and most important journal that publishes scientific research papers on the subjects of solid mechanics and stress analysis, and also the flagship journal of the American Society of Mechanical Engineers. It's the oldest and most important of their

16:00:37 journals.

As I mentioned, I was its editor-in-chief for ten years and I supervised a panel of associate editors to carry out the process of peer review to ensure the papers we published were of satisfactory standard. And we rejected

16:00:55 about twice as many papers as we accepted, so we had a very high level of stringency in the reviews, the review process.

Q Okay. Thank you.

Now, in addition to teaching engineering students, do you practice engineering?

16:01:14 A Yes, I do. As I've mentioned already, I carry out

16:01:18 research in engineering. But I also am a consultant in mechanical engineering and material science to companies that work in that area.

Q Do you consult with medical device companies?

16:01:31 A Yes, I do. I've consulted for about 15 of them over a period of about 30 years, and I've also consulted for about another 15 companies which are in areas other than medical implant devices.

Q What types of implants have you consulted on?

16:01:48 A I've consulted on prosthetic heart valves; stents, the cardiovascular stents that go into your blood vessels and so on; and also on breast implants. And I've also done consulting on an inferior vena cava stent that is used to stabilize a prosthetic tricuspid heart valve.

16:02:21 Q When you consult with companies, can you give us an idea of the types of professional activities you engage in. Do you review designs, for example?

A Yes. I review the designs they're undertaking, proposing. I make suggestions for how to possibly improve the designs. I

16:02:37 make assessments of potential problems with the designs and the possible ways in which the design or the device that's eventually made will fail or not function as it should.

I review the testing that the company carries out for the same purpose of assessing problems and possible failures.

16:03:05 And I also review their calculations and their analysis that's

16:03:11 carried out to support both the designs and testing of their devices.

Q You told us earlier, and you gave us a basic understanding of the subjects you teach and the type of engineering analyses 16:03:24 that you teach, and we'll talk in more detail how those apply to this case, but when you consult with medical device companies, companies that are making devices that go into the human body, as an engineer do you take steps to learn about the anatomy where the device is going to be placed?

16:03:43 A Yes, that's correct. I make an assessment of the environment and the conditions that the device is going to experience and I take into consideration what that environment will impose on the device, the forces and deformations and distortions that the device will be subjected to, and I take 16:04:07 that information into consideration when I consider whether the device will function satisfactorily or whether it will have problems and potentially fail in some way.

Q Now, the work that you've done here in this court case, number one, are you paid for your time?

16:04:27 A I am.

Q And have you approached the work you were required to do in this case any differently than when you are asked to consult with a medical device company?

A No. I've approached this work in very much the same way 16:04:44 as I approach and do the work I carry out for the companies

16:04:47 that I consult with.

I've reviewed the designs and testing protocols and plans that Bard had in place for their inferior vena cava filters and I've reviewed the testing that they've carried 16:05:04 out. I made assessments of the conditions and the environment that the device will experience and I've made an assessment of the problems and the failure modes which may arise in association with the device.

I've reviewed the designs and I've made assessments 16:05:25 of those designs. And to undertake those assessments I've carried out my own calculations, which is something I also do when I'm working with the companies that I consult for.

Q When you are coming -- when you are doing work as an expert in a court case like this, how often do you do that?

16:05:46 A Well, I did a small amount of work about 25 years ago in a couple of cases. One was a bicycle accident and the other was a failed knee prosthesis. And then about 15 or more years I did no litigation work.

And, by the way, those two cases didn't go anywhere 16:06:06 in terms of trial or any serious activity, so they were quite brief episodes.

And I went for ten or 15 years without any activity in that area. And more recently I've been involved in the Bard litigation, as you know, and in some other litigation 16:06:26 currently that's going on.

16:06:28 Q Are you involved in any other cases involving IVC filters?
A Yes. I'm involved in cases that involve IVC filters manufactured by Cook Company.
Q Now, how much of your income do you derive from acting as
16:06:47 an expert witnesses in these type of cases and court cases?
A Less than 15 percent over the last eight or so years.
Q And you're being paid for your time in this case; correct?
A I am, yes.
Q How are you being compensated?
16:07:04 A I'm paid $400 an hour for preparatory work and $800 an hour for events such as today when I'm testifying.
Q Is that amount any different than what you charge medical device companies?
A I charge medical device companies $400 an hour, so I
16:07:21 charge the same rate to them as I'm charging for the preparatory work. Since I don't do any testifying for the companies I consult with, I don't charge them the $800 an hour figure.
Q Now, I want to talk to you for a moment about how
16:07:42 mechanical engineers do their work and approach engineering issues. Are there principles that engineers are trained to follow and that medical devices should look at when they are designing medical devices?
A Yes, there are.
16:08:01 Q And where are the -- what are those principles or rules,

please.

A Well, the first and most important principle is that patient safety is paramount. The next rule is that the engineer engaged in this should investigate thoroughly the conditions and environment that the device will experience.

With that information in hand, the engineer should next make assessments of problems that may arise with the device and potential failure modes that may occur as a consequence of the device's conditions and the environment within which it will operate.

Q So -- so is there a step where device companies and their engineers should look at a device to anticipates problems that may arise?

A Yes. They should, of course, look at the design as they develop it to anticipate such problems. Once the design is some way along, it's very important to carry out tests of the device to assess the potential problems and the potential failure modes that may be in place for this device.

And in the testing it's important to replicate very carefully the conditions that the device will experience and the forces and deformations and so on that it will experience as a result of the environment that it will be placed in.

Q And are there rules that should be followed by medical device companies in the testing of a device for the reasons you discussed?

16:09:47 A Yes. They should thoroughly test the devices and they should use what we call worst-case conditions among the tests that they're doing, and it's most important to do the worst-case conditions test to ensure that the potential
16:10:05 problems and potential failure modes are fully explored in the testing which is undertaken.

Q What do you mean by worst-case conditions?

A Well, worst-case conditions are the conditions that are reasonably foreseeable that will cause the greatest difficulty
16:10:25 of stress or the greatest problems for the device.

So a simple example would be conditions that would impose the highest level of forces that the device might experience and that might be reasonably foreseen in the environment and conditions that the device will be used in.

16:10:45 Q Should tests used by medical device companies in the development of an implantable medical device include testing that requires an understanding of the environment of use?

A Yes. They should -- the engineer who is engaged in this activity should investigate thoroughly the conditions that the
16:11:06 device will experience. And if there is inadequate knowledge of conditions that the device will experience, then steps should be taken to find out more about that environment.

The tests and calculations should be designed to replicate the conditions as closely as possible and, as I
16:11:31 mentioned before, should be chosen to ensure that worst-case

16:11:35 conditions are encompassed in the kind of testing and calculations that are carried out.

Q Well, when you talk about foreseeable worst-case conditions and the requirement of testing, is that like the

16:11:47 requirement for auto companies to test for front-end crashes?

A That's right. If you're designing and developing a car, you need to consider the ways it can be compromised, such as in a crash. You have to think about front-end crashes, side impacts. Rollovers, perhaps. So even if every crash is a

16:12:11 little bit different, you have to have a robust design that will take care of all of the possibilities that are reasonably foreseeable.

And it's also appropriate to build in some safety features that will help to ameliorate the consequences of bad

16:12:29 things happening to the car. So things like airbags and seatbelts are appropriate as part of the design of the car.

Q In terms of IVC filters, if you don't mind. In terms of IVC filters and testing foreseeable worst-case conditions, what is the environment that should be looked at and

16:12:51 understood in order to develop the appropriate tests?

A Well, the environment is the inferior vena cava and the organs and tissues around it, which are in the abdomen, which interact with the inferior vena cava as people move and breathe and so on.

16:13:13 Q Are there sources out there that are understood and

16:13:15 recognized by engineers and medical device companies, sources for the foreseeable worst-case condition?

A Yeah. The principles of how to approach a design and the importance of implementing worst-case conditions in testing and assessments and so on is something that is sourced from organizations such as the American Society of Mechanical Engineers, which emphasizes the importance of doing things like worst-case condition testing and analysis.

Specifically -- and American Society of Mechanical Engineers has a fairly big footprint in the medical devices area. There are perhaps more specialized organizations such as the International Medical Device Regulators Forum, which has generated a series of recommendations as to how to approach the design and testing of medical devices, and it includes the principle of worst-case condition testing and analysis.

And then authoritative textbooks such as Dieter and Schmidt and other design and education textbooks emphasize the importance of identifying worst-case conditions and implementing them in the process of design analysis and testing.

Q Is worst-case condition, testing for that, a basic rule of design in engineering for medical devices?

A It's a basic rule. It's a fundamental principle of design and development of medical devices.

16:15:05 Q We're going to go into detail, but the work you've done in this case, did you look at the design and testing that Bard did on its IVC filters?

A I did, yes.

16:15:11 Q And I think you told us you looked at filters, including the Simon Nitinol filter, the Recovery filter, the G2, G2X, Eclipse, and other filters; correct?

A That's correct, yes.

Q And based upon your review of the testing that Bard did on

16:15:30 its filters, did you -- do you have an opinion as to whether Bard followed the basic rule of testing for the worst-case condition?

A I have an opinion, and that opinion is that they did not follow the basic and fundamental rule of carrying out

16:15:44 worst-case condition testing and analysis of their IVC filters.

Q Can you give us an example.

A Well, for example, when the Recovery filter, which is the first in the line of filters that we're here to talk about,

16:16:02 when it was being developed, a test was carried out in which it was subject to forces applied to it that would expand it and contract it in a way that it would experience when it was in the inferior vena cava, subject to a person breathing, which causes the vena cava to expand and contract.

16:16:28 And in that test they did not include conditions such

as tilting, such as the limbs of the filter perforating through the wall of the IVC. They did not include endothelialization of the filter to the wall of the IVC in that test. And these are all conditions which would make the conditions of the test much worse and apply worst-case conditions to the filter. And these are all foreseeable conditions that the filter will experience once it is implanted in the human body.

Q All right. So let's go to a different area.

And let's talk about the work you did in this case to arrive at your opinions. Could you tell us how you did that. How you approached your role in this case and the things that you did.

A Yes. So I first of all obtained and read a very large number of documents which had been generated by Bard in the process of their design and development of this series of filters that we're discussing. And those documents looked at things like the definition of the design and it's nature. In other words, the shape, size, the material the device is made from.

I looked at the documents that describe the testing that the device was put through in the process of its development, and I read documents that describe the calculations that engineers carried out for Bard to make assessments of the performance of the device.

16:18:27 I also read expert reports and depositions and testimony from other experts in this litigation and I read scientific and medical literature that is concerned with the behavior of IVC filters, especially the Bard line of Recovery, 16:18:51 G2, G2X, and Eclipse filters. And I --

Q Now -- go ahead.

A I made assessments of the designs myself and I carried out calculations of my own to make such assessments.

Q Let's talk about that. First I want to ask you this: Did 16:19:13 you look at specific types of tests in your analysis?

A Yes. My focus in my work was to look at the protocol bench tests and calculations. And in this case the calculations are what we called finite element analysis calculations. That's often abbreviated FEA, and I think 16:19:34 you'll hear that from me quite a lot.

So, as I said, my focus was on bench tests and finite element analysis calculations.

Q So I almost hate to open this up, but what is a finite element analysis?

16:19:49 A Finite element analysis is a computer method of doing calculations that will predict what will happen to a device such as a filter when forces are applied to it or it is caused to undergo distortions and deformations. It's a computer method of doing calculations that embody basic principles of 16:20:16 physics and materials behavior. And it's actually just a

computer version of calculations that you can do on a piece of paper. The principles of the calculations are identical to mathematical calculations that analyze the same principles of physics and materials behavior.

Doing the calculations in the computer is often convenient because the calculations are sometimes very complicated and the computer can do those calculations much faster than doing algebra on a piece of paper.

Q But do engineers do it in both forms, computer and also by hand?

A Yes. It's very wise to do the calculations using both methodologies because there are different advantages from doing different kinds of calculations.

When I do calculations on a piece of paper, I can often do that because the calculations are sufficiently straightforward that they're amenable to that kind of analysis.

And by doing that kind of calculation, I can get much greater insight, and perhaps cover much more territory, in terms of different shapes and sizes and different possibilities that can occur in the calculation.

But then there are other situations where the situation of the calculation is much more complicated. And then doing the calculation by the computer becomes the option that is best in that case. But, as I said, it's often

important to do the calculations both ways so that one serves as a check on the other.

Q Did you do computer calculations and hand calculations in this case?

A I did. I did both computer calculations and calculations by hand.

Q And what was your objective in performing those calculations?

A My objective was to investigate the worst-case conditions that the filter would experience in terms of what might happen to it that would cause it to fail. Those failures would include the possibility of it tilting, the possibility of it migrating or moving in the vena cava, the possibility of the filter perforating the wall of the vena cava by cutting one of its limbs through the tissue of the wall. And also the possibility of a fracture occurring so that a piece of the filter breaks off and is loose in the body and can move elsewhere, such as to the heart or other organs.

Q So can you just explain to us how an engineering calculation like an FEA, finite element analysis, or the handwritten version will help a medical device company understand if its device will fracture. How does that even work?

A Well, it is -- it is -- the calculations enable you to thoroughly investigate the conditions that the device or the

16:23:32 filter will experience.

In almost all circumstances it's possible to assess how a device will deform, the forces it will be subject to, and the consequences that those deformations and forces will
16:23:52 have on the device.

There's a large amount of both theory and experimental results that guide one in terms of how that behavior will occur, and so one can undertake a calculation that will predict how such responses will take place. And I
16:24:18 can demonstrate this with a paper clip.

Q Is this a good time -- I think we've got a few minutes left. Is this a good time -- hold that. Is this a good time to talk about stresses and strengths?

A Yes, this is a good time.

16:24:32 Q All right. And so can you illustrate to the jury what stresses and strains mean to engineers.

A Yes. So I can demonstrate with this rubber band. And as I'm sure you're all familiar with rubber bands, when you stretch them they get longer. So an engineer characterizes
16:24:51 that stretching by what we call strain. So strain is a measure of how something will lengthen or distort or change shape.

Q Let me stop you there on that point.

You're showing us something on a rubber band. Do the
16:25:09 same principles apply to something more solid such as metal,

steel, wood?

A Yes. I've got a wooden dowel here and a threaded steel shaft. Again, I'm sure you're familiar with the fact it's quite easy to stretch a rubber band.

Q That's strain what you're showing us there; right?

A That's strain.

Q All right. Then what would you do to illustrate stress?

A If I try to stretch the dowel, it's very hard. It is actually stretching, but you can't see. Even I can't see from close up. However, I can bend it. I don't think you can see much bending, but I am distorting it.

So this is much more difficult to distort, but it is possible for me to distort it. So the strains that I'm managing to achieve are much less in this case with the wooden dowel.

But then if I move to the steel shaft, I am actually distorting it, but you can't see it and I can't see it, and the only way that you would be able to measure it is with a microscope, perhaps even an electron -- what's called an electron microscope.

I can't even bend this. So it's much more difficult to deform and therefore the strains that I'm managing to impose on the material are much less. Typically, the bigger the strain that you impose on the material, the more dangerous is the situation.

16:26:39 So if I could stretch this enough -- I don't want to break it because it will fly over and hit Mr. O'Connor in the face, but --

Q And then I'll experience stress.

16:26:51 A But if I stretch it enough, it will break. And that illustrates the point that big strains can be bad for materials.

Q All right. Can you tell us what stress is --

A Okay.

16:27:02 Q -- because sometimes they seem interchangeable. But are they?

A No, they're not.

In everyday life they are, but we engineers distinguish between stresses and strains.

16:27:15 So stress measures forces. Forces are things like gravity and the effect, for example that pistons have when they drive the shaft of an engine.

So there's lots of devices that -- and natural conditions that impose forces on other objects.

16:27:37 So at the same time I'm straining this rubber band, I'm applying a force with my fingers. My muscles are generating that force. And the force is, if you like, what is stretching the material.

So two things happen simultaneously. Stress and

16:27:56 strain happen simultaneously.

16:27:59 However, strictly speaking, stress measures the intensity of the force. It's the force divided by the cross-sectional area of the thing that is being stretched.

And so I'm applying a certain level of stress to this
16:28:16 object and it extends.

And I can apply a certain level of stress to this object. You can't see the extension, but I can measure, I can compute the force over area and therefore the stress.

And I can do the same thing to the steel shaft.

16:28:34 And I'll say one more thing, which is just as excessive strains are bad for materials, excessive stresses are bad for materials and cause -- and can cause them to fail and fracture.

Q And I just have one more question.

16:28:50 Are you telling us that engineers have the ability through these calculations to understand what stresses and strains are going to be imposed on a device when placed in a specific environment?

A That's exactly what these things called finite element
16:29:07 analysis calculations do, and it's exactly what I do when I do the calculations on a piece of paper.

Q And when we return, are you going to explain to the jury how those calculations can tell a company like Bard what will happen to an IVC filter when it's put in the environment of a
16:29:23 vena cava?

16:29:23 A Yes, I will.

MR. O'CONNOR: Your Honor, I could go into another area, but --

THE COURT: No, we'll break.

16:29:32 Ladies and gentlemen, we will plan to resume at 9 o'clock tomorrow morning. Please remember not to investigate the case or discuss it. We will see you then.

(The jury exited the courtroom at 4:30.)

THE COURT: You can step down, Doctor.

16:30:12 Please be seated.

Counsel, is there an allocation of the Rogers deposition time to the defendants?

MS. SMITH: Yes.

Your Honor, eight minutes and eight seconds for the

16:30:28 plaintiffs. For defendants, it's two minutes and 41 seconds.

THE COURT: Okay. Thank you.

All right, Counsel, as of the end of today plaintiff has used four hours and 42 minutes. Defendants have used three hours and 26 minutes.

16:32:37 I wanted to mention, in case you didn't see it, I received an order today from the panel on multidistrict litigation granting the remand of the mature cases. And the order -- I've got a copy if you want it. But the order --

Actually, this is the conditional order that we

16:32:56 printed, Jeff. There's a final order as well, I think.

16:33:04 They also notified us the final order is out.

It says that the parties will need to provide the clerk of this Court with a stipulation on the contents of the record to be remanded. So you all need to figure out what 16:33:20 portion of the MDL record should go back to these districts. I assume it can be the same record for all of them but you need to work that out and give the stipulation to our clerk here so they know what to send to those courts.

Anything we need to address before tomorrow morning?

16:33:43 MR. O'CONNOR: Nothing from plaintiffs, Your Honor.

MR. ROGERS: Nothing from defendants, Your Honor.

THE COURT: All right. See you at 8:30.

Counsel, one other matter. What you've just been handed is a list of standard Wisconsin jury instructions that 16:34:19 we can't access and that you cite.

MS. HELM: Your Honor, they're only available in hard copy. I'll be happy -- it's a three-volume notebook.

THE COURT: All we need are those.

MR. O'CONNOR: We have the volumes too.

16:34:34 THE COURT: If you would just copy those. We've decided those are the key ones that we need to be able to look at for jury instructions. If you could just get us a copy of those.

MS. HELM: We borrowed them first and we bought a 16:34:49 set. They're big and red.

16:34:52 MR. O'CONNOR: Wisconsin rejects electronic -- they have a lot of trees up there.

MR. ROGERS: Keeping it old school.

THE COURT: By the way, Mr. O'Connor, if you could be
16:36:11 ready tomorrow morning if you want to go into the safe versus dangerous issue with Dr. McMeeking, if you could show me where that is in the report.

MR. O'CONNOR: I was just planning on that.

THE COURT: That would be great. We'll talk about
16:36:22 that in the morning.

(Recess taken at 4:37.)

(End of p.m. session transcript.)

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C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 20th day of September, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter